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UNITED STATES PATENT APPLICATION

of

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for

CATHETER WITH VALVED DISTAL TIP

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BACKGROUND OF THE INVENTION

1. The Field of the Invention

This invention pertains to medical catheters adapted for transcutaneous or complete implantation in the body of a human medical patient to provide access through such catheters to the interior of the body of the patient. More particularly, this invention pertains to catheters having a lumen that is closed at the distal end thereof and, therefore, that must be correspondingly provided with a valve structure that is capable of effecting fluid communication between that lumen and regions inside the body of the patient.

2. Background Art

Catheters are used extensively in the medical field to facilitate the performance of recurrent therapeutic tasks inside the body of a patient.

By the creation of only a relatively small incision, a catheter can be implanted in the body of a patient and used to deliver fluid directly to a predetermined location, either within the cardiovascular system, the peritoneal cavity, or some organ, such as the stomach, the heart, the liver, the brain, or the reproductive tract. Alternatively, or in addition thereto, such an implanted catheter can be used to periodically sample fluids from these locations, to relieve pressure by draining fluid, to withdraw fluids for extracorporeal processing on an ongoing basis, and to monitor internal body conditions, such as pressure, temperature, or rate of fluid flow.

A typical catheter used in performing procedures of the types mentioned above includes an elongated, flexible catheter tube having one or more fluid flow passageways, or

lumens, extending longitudinally through that catheter tube. During implantation, an end of the catheter is inserted into the body of a patient through an incision or a body orifice, thereby to enter into a body cavity or an internal passageway, such as a blood vessel in the cardiovascular system. This inserted end is referred to as the distal end of the catheter. The distal end of the catheter is advanced within the body cavity or along the internal passageway, until the distal end of the catheter is positioned at a predetermined location at which intended therapeutic activity is to be conducted. Fluid containing medication, nutrients, or cleansing agents are then introduced from the distal end of the catheter and delivered through the lumen or lumens of the catheter to that predetermined location.

The end of a catheter opposite from the distal end is referred to as the proximal end. Once the distal end of a catheter has been implanted at a predetermined location as described above, the proximal end of the catheter is attached to a medical device that is appropriate to the specific task and manner of use to which the implanted catheter is to be applied. On some occasions, the proximal end of the catheter with this medical device attached thereto remains outside the body of the patient. In other situations, the medical device attached to the proximal end of the catheter is implanted subcutaneously in the body of the patient.

Increasingly common is the use of catheters in this manner to access the cardiovascular system of a patient. The vessels of the cardiovascular system are susceptible on the basis of the fluid conditions and quality of blood therein of being classified into three subsystems.

The pulmonary subsystem of the cardiovascular system circulates blood from the heart through the lungs, where the blood is oxygenated, and back to the heart.

The arterial subsystem of the cardiovascular system carries freshly oxygenated blood under high positive pressure fluctuations from the heart to the capillary systems in the organs and muscles of the body. The positive pressure in the arterial subsystem is highest closest to the heart, reducing gradually with remoteness from the heart as the vessels of the arterial subsystem subdivide into smaller and smaller arteries and then enter capillary systems.

The venous subsystem of the cardiovascular system returns blood to the heart from the capillary systems through veins under the influence of a relatively low, pulsating pressure. The veins of the venous subsystem merge one with another, increasing in size in the direction of the heart. Blood flowing in the venous subsystem of the cardiovascular access system has been depleted of oxygen during the transit of the blood through the capillary systems of the body.

As the types of medical procedures multiply that require venous access, catheter access to the venous subsystem of the cardiovascular access system increases in frequency and in sophistication. Vascular access catheters for this purpose can be narrowly referred to as venous access catheters. The implantation and subsequent use of such venous access catheters permit the monitoring of blood pressure, the sampling of blood, and the infusion of medicaments or nutrients at almost any location in the venous subsystem of the cardiovascular system, even locations that are central to the venous subsystem in the vicinity of the high volume blood flow passageways immediately interconnected to the heart.

Venous access catheters are thus implanted in the body of a patient with the distal end of the catheter positioned at some such predetermined location in the venous subsystem. The majority of the length of an implanted venous access catheter proximal from the distal end resides in contiguous veins of the venous subsystem, usually leading away from the heart. In

this manner, the proximal end of an implanted venous access catheter will exit the cardiovascular system remote from the heart, thereby to be accessible to medical practitioners at locations that are distant from delicate viscera.

Experience with such practices has lead to the development of highly specialized, technologically sophisticated venous access catheters that are designed to meet needs associated with specific therapeutic procedures. Key to the utility of an implanted venous access catheter is that the lumen or lumens of the catheter be in fluid communication with some region inside the venous subsystem on the exterior of the catheter body. In many instances, fluid communication between the lumen of a venous access catheter and that region inside the venous subsystem of a patient on the exterior of the catheter is attained by way of an aperture that is open on a permanent basis through the circumferential outer wall of the catheter or through the distal tip of the catheter.

The desirability of a permanently open aperture is compromised, however, by the continuousness of the fluid communication that is maintained through such an aperture between the proximal end of an implanted catheter and the interior of the body of the patient. The pathway along which this continual fluid communication is effected represents a route by which infection can enter the body of the patient. That pathway is also a conduit through which fluid can uncontrollably escape from the venous subsystem of the patient. Accordingly, the need exists to control on a selected basis the times at which a working fluid communication is made to exist between the proximal end of an implanted venous access catheter and any region inside the venous subsystem.

Only outside the body of a patient, at the extracorporeal portion of the proximal end of an implanted venous access catheter with a permanently open aperture, is it possible to control the fluid communication to the vascular subsystem. Frequently, a medical device secured to the proximal end of an implanted venous access catheter will incorporate some type of closure mechanism that is selectively operable by medical personnel toward this end. Alternatively, or in addition thereto, an extracorporeal portion of the proximal end of the catheter that is accessible to medical personnel is provided with a catheter tube clamp that is used on a selective basis to press together the opposite walls of the catheter body, thereby to prevent fluid flow in the lumen or lumens between those walls.

Tube clamps can impose undesirable wear on the proximal end of an implanted catheter. Tube clamps also require continual vigilance on the part of attending medical personnel to ensure reliable closure on all occasions and to detect promptly any inadvertent failure of the closure function of the clamp. Such drawbacks exist to a degree, even in medical devices that are attached to the proximal end of an implanted catheter and that incorporate closure mechanisms therein.

Additional concerns are presented where an implanted venous access catheter with a permanently open aperture is to be used only on an intermittent basis. Whenever a venous access catheter with a permanently open aperture is not in actual use, the lumen associated with that aperture continues to maintain fluid communication through that aperture with the cardiovascular subsystem. At times of unuse, such a lumen is filled with a relatively static column of fluid. Through the permanently open aperture, constituents of body fluid diffuse into that column of fluid from the distal end thereof. As the column of fluid may be substantially

stationary for extended periods of time, a situation of stagnation can arise in which elements of body fluid become attached to the rim of the permanently open aperture and to the interior of walls of the lumen adjacent thereto. Clotting of blood factors can easily occur, and a thrombogenic buildup can develop that is the cause of several corollary problems.

The clotting process can lead to a complete obstruction of the otherwise permanently open aperture, or of the associated lumen. This can render the implanted venous access catheter useless in an emergency, or require the removal of the catheter and the reimplantation of another in the place thereof. Removal and reimplantation causes the patient unnecessary pain, increases the cost of maintaining access to the cardiovascular system, and undesirably consumes the time and attention of attending medical personnel.

The risk to a patient may be actually more severe when a catheter lumen is only partially obstructed by thrombosis. Under such circumstances, fluid is usually forced through the partially obstructed lumen from the distal end thereof. Often this will break the thrombosis loose from the catheter, causing the thrombosis to flow as a clot through the cardiovascular system, until the clot lodges at an unpredictable location in a small or partially obstructed blood vessel. If the thrombosis lodges in such a vessel in the heart, lung, or brain, serious complications may result, such as a heart attack, a pulmonary embolism, or a stroke.

Maintenance measures have been adopted to forestall the development of thrombosis in the lumen of an implanted venous access catheter that is not in frequent use. In the most common of such maintenance measures, the lumen is flushed on a periodic basis from the distal end of the catheter with a saline solution. Such a saline flush can be supplemented by the infusion of a quantity of heparin solution into the column of fluid that is to reside in the lumen

of the catheter until the next subsequent use or maintenance thereof. Still, the heparin at the distal end of this column of fluid, where the fluid communicates through the permanently open aperture with the cardiovascular system, diffuses over time into the cardiovascular system, being replaced in the lumen of the catheter by constituents of body fluid that can eventually give rise to thrombosis. This approach to maintaining the long-term placement of a venous access catheter with a permanently open aperture interior of the body of a patient is thus labor intensive and of limited duration in effectiveness.

One approach to reducing the need for such maintenance activities has been to eliminate any permanently open aperture between the lumen or lumens of a vascular access catheter and the venous subsystem of the patient. Doing so also relaxes the urgency of paying close attention to closure mechanisms at the extracorporeal portion of the proximal end of an implanted venous access catheter.

The permanently open aperture is replaced by a selectively operable valve structure that isolates the column of fluid in the associated lumen from the interior of the body of the patient when the lumen is not in actual use. The distal end of a venous access catheter is a relatively tiny structure that is subjected to continual agitation by turbulence in the blood flowing past the distal end of the catheter and by physical movement of the patient. Valving structures appropriate for use with an implanted venous access catheter must, therefore, cope successfully with a rare combination of physical and chemical conditions.

An elegant valving structure developed for this purpose by LeRoy E. Groshong and Ronald J. Brawn involved a catheter tube with a closed distal end provided with a longitudinally extending slit formed through a circumferential outer wall of the catheter. The slit extended

from the exterior of the catheter through the outer wall to a lumen in the catheter body. The opposed faces of the slit normally remained in abutting sealing engagement, isolating any column of fluid in the associated lumen from the region in the body of the patient outside of the catheter tube in the vicinity of the slit. Through persistent refinement and experimentation, such slit structures were developed as were capable of functioning as reliable two-way, three-position valves. Advantageously, these valves were constructed in an integral manner from the very material of which the associated catheter tube had been manufactured.

In response to the development of a predetermined positive pressure differential between the lumen on one side of such a slit and the region in the body of the patient on the other side of the slit, the slit faces would separate outwardly, infusing fluid from the lumen through the gap between the slit faces into the region in the body of the patient on the exterior of the catheter. This was the outwardly open position that could be assumed by the slit when functioning as a valve.

When the positive pressure in the lumen was reduced to such an extent that the predetermined positive pressure differential required to sustain the outward opening of the opposed faces of the slit was lost, then those opposed slit faces would resume sealing engagement, assuming the closed position of the slit when functioning as a valve.

The development of a predetermined negative pressure differential between the lumen on one side of such a slit and the region in the body of a patient on the other side of the slit would cause the opposed faces of the slit to separate and open inwardly, permitting the aspiration of fluid from the exterior of the catheter through the gap between the faces of the slit

into an associated lumen of the catheter. This was the inwardly open position of the slit when functioning as a valve.

When the negative pressure in the lumen was reduced to such an extent that the predetermined negative pressure differential required to sustain the inward opening of the opposed faces of the slit was lost, then those opposed slit faces would resume sealing engagement, assuming the closed position of the slit when functioning as a valve.

The extreme ends of such a slit structure do not separate at all during aspiration or during infusion. At the extreme ends of such a slit structure, the opposed faces of the slit meet at slit face junctions. Thus, the inward or the outward separation of the opposed faces of a slit occurs, not to a uniform extent along the length of the slit, but to an extent that ranges from a maximum at the center of the length of the slit to a minimum somewhere away from that center toward each slit face junction.

Reliable valving using a slit formed through the circumferential outer wall of a catheter ultimately required delicate adjustments to the amount and the softness of the catheter material at the slit. On occasion, enhanced softness was obtained through chemical treatment, as, for example, through a timed soak of the material at the slit in dimethylsiloxane. Further improvements in the reliability of the valving attainable using a slit structure accrued from the use of various non-circular shapes in the transverse cross section of the lumen with which a slit was associated, at least in the vicinity of the slit. This correspondingly required the precise positioning of the slit in relation to any significant features of that noncircular transverse lumen cross section.

The development of a slit in the circumferential outer wall of a catheter that would reliably function as a valve solved many of the problems associated with catheters having permanently open apertures. Nonetheless, the consequent widespread use of such slits revealed problems that could not have been anticipated prior to the successful evolution of a slit structure that would reliably function as a valve.

For example, the portion of any lumen distal of an associated slit in the circumferential outer wall of a catheter tube becomes a region in the lumen that is not easily flushed by fluid flowing outwardly or inwardly through the slit. Maintenance flushing with saline and heparin solutions can reduce the threat posed in these relatively stagnant regions, but thrombosis can develop quickly whenever flushing of these relatively stagnant regions is incomplete, and microorganisms can proliferate there, becoming a source of contamination. In some catheter designs, the portion of any lumen distal of an associated slit is filled with a plug of catheter material to reduce this problem. Even the use of such a plug of catheter material, or the positioning of a slit in the circumferential outer wall of a catheter tube as close as possible to the distal end of the associated lumen, does not prevent stagnation at the very distal end of that lumen, except possibly when combined with frequent and conscientious maintenance flushing of the lumen.

The formation of a slit in the circumferential outer wall of a catheter tube has other potential structurally compromising consequences.

A slit tends to reduce the ability of the portion of the length of the catheter tube in the vicinity of the slit to maintain the intended configuration of the cross section of the catheter tube. This can be countered through the use of catheter tubing with a stiff or thick

circumferential outer wall, but such properties in the circumferential outer wall of a catheter tube are contrary to those desired in the vicinity of a slit that is intended to function as a valve. By contrast, the outer wall of a catheter tube in the vicinity of such a slit needs to be relatively delicate and sensitive to fluid pressure differentials.

On the other hand, overly reducing the robustness of the circumferential outer wall of a catheter tube in the vicinity of a slit can lead to inadequate support for the catheter walls on either side of the slit. This result will impair the sealing effectiveness of the opposed faces of the slit in the closed position thereof. A thin or soft circumferential outer wall in a catheter tube also exhibits enhanced susceptibility to kinking at the slit and a tendency to collapse under the negative pressure differentials associated with aspiration. Lumen collapse during aspiration generally will defeat the functionality of the inwardly open position of the slit when used as a valve. A kink at a slit in the circumferential outer wall of a catheter tube can cause the slit to remain open for an uncertain duration, or to be damaged permanently.

The design constraints imposed on catheter structures in the vicinity of a slit in the circumferential outer wall of a catheter tube are thus bewilderingly contradictory.

Even if a slit structure is capable of reliably functioning as a valve, the use of that slit as a valve causes problematic interactions of the associated venous access catheter with the surrounding living tissues in the body of a patient. Such surrounding living tissues include the walls of the vein of the cardiovascular system in which the catheter is disposed, the cells in the blood flowing in the vein, and the fibrin sheath that commonly develops about a venous access catheter that remains implanted for an extended duration.

The fibrin sheath is produced as a consequence of normal and healthy reactions of the immune system of the body of the patient directed toward isolating foreign bodies therein. At the venipuncture site, where the catheter tube of a venous access catheter enters the cardiovascular access system, the cells of the venous wall in combination with the cells of the blood commence promptly to heal about the intruded catheter body, which is perceived rightly by the immune system as being a foreign body. A sheath of fibrin material and other cellular constituents begins to grow from the interior wall of the venipuncture site along the outside of the implanted catheter tube. While remaining attached to the wall of the vein at the venipuncture site, the fibrin sheath grows gradually along the length of the catheter tube toward the distal end thereof. The fibrin sheath does not tightly encase the outer surface of the circumferential outer wall of the catheter tube, but trails in the flow of venous blood loosely encircling an ever-increasingly larger fraction of the length of the catheter tube.

Initially, the fibrin sheath is quite short, restricted in length to an area immediately adjacent the site at which the catheter tube extends through the venipuncture site into the venous subsystem. Over time, however, the fibrin sheath grows in length until the fibrin sheath reaches or even extends beyond the distal end of the catheter tube. While it may take some weeks after the implantation of a vascular access catheter for a fibrin sheath to reach such a length, once that length has been achieved, the fibrin sheath tends to interact undesirably with any slit in the circumferential outer wall of the catheter when that slit is used as a valve.

During infusion, a jet of fluid passes outwardly through the slit. The jet of fluid is directed substantially normal to the longitudinal axis of the venous access catheter and to the longitudinal axis of the vein in which the catheter is disposed. If the fibrin sheath has not yet

grown along the exterior of the catheter tube to the slit, the infused fluid jet may be directed at the interior of the vein wall, possibly causing irritation of the intimal layer thereof or loosening particles of plaque and other deposits. The resulting debris floats through the cardiovascular system until lodged in small or partially occluded blood vessels, much in the manner of a floating thrombosis.

Simultaneously, the emission of a fluid jet directed normal to the longitudinal axis of a catheter tube causes the portion of the catheter tube at the slit to be driven in a direction opposite the momentum of the fluid jet, toward and against the wall of the vein opposite that impinged upon by the fluid jet. Depending upon the positioning of the slit among the bends and incoming tributaries of the vein, such impacts of the catheter tube against the intimal layer can cause bruising and the generation of floating debris.

When the fibrin sheath associated with an implanted venous access catheter has reached to or distally beyond a slit in the circumferential outer wall thereof, these interactions of an infused fluid jet with the immediately surrounding vein walls are moderated to a degree by the fibrin sheath. In these circumstances a fibrin sheath provides a measure of protection for the immediately surrounding intimal layer of the vein from the dynamic behavior of the catheter tube during infusion. In general, however, a fibrin sheath causes problems in the long-term use as a reliable valve of a slit in the circumferential outer wall of a catheter tube.

The distal end of the fibrin sheath rarely closes about the distal end of an implanted catheter tube. As a result, infusion through a slit in the circumferential outer wall of the catheter tube is usually successful, even with the presence of a fibrin sheath encircling the catheter tube at the location of the slit. An extremely gentle touch is required on the part of attending medical

personnel, however, to effect the infusion of fluid through a slit formed in the circumferential outer wall of a catheter tube surrounded by a loosely fitting fibrin sheath. A fibrin sheath is easily torn by any forceful fluid jet infused out of a slit in the circumferential outer wall of a catheter tube. A fibrin sheath may even be severed into distinct, free floating lengths by a fluid jet from such a slit. Damage incurred by a fibrin sheath as a result contributes to floating debris in the cardiovascular system. That resulting floating debris that can be relatively large, particularly where the fibrin sheath has grown distally beyond the location of the slit through which the fluid jet is infused.

During aspiration, different problems are apparent in relation to slits in the circumferential outer wall of a venous access catheter. If the fibrin sheath has not yet extended along the exterior of the catheter tube to a slit in the circumferential outer wall of the catheter tube, then the aspiration of fluid from the surrounding vein through the slit will tend to attract the catheter tube toward the wall of the vein that faces the slit. If the open slit as a result contacts the wall of the vein, the intimal layer of the vein can enter the open slit, terminating aspiration. Portions of the intimal layer are drawn into the slit by the negative pressure differential required for aspiration. Such portions of the intimal layer are injured as a result.

In many cases, the application of a positive pressure differential through the lumen associated with a slit blocked in this manner can clear the slit for future aspiration. Nonetheless, depending upon the location of the slit among the curves and entering tributaries of the vascular subsystem, a failure to immediately detect the cessation of aspiration can cause substantial venous wall damage. Medical practitioners will typically tend initially to apply increasingly

greater negative pressure to the proximal end of a catheter that is not aspirating properly, rather than backing off the negative pressure and applying a positive pressure instead.

If a fibrin sheath has grown to or distally beyond a slit in the circumferential outer wall of a venous access catheter, then these interactions are somewhat moderated by the fibrin sheath. Nonetheless, it is during efforts at aspiration that the fibrin sheath most regularly impedes successful functioning of a slit as a valve. As the fibrin sheath encircling a slit in the circumferential outer wall of the catheter is loosely floating in fluid, the fibrin sheath is quite easily drawn by aspiration toward and into the slit. The relatively gossamer structure of the fibrin sheath enables the fibrin sheath to be drawn deep into the lumen associated with a slit used for aspiration before that fact is apparent to attending medical personnel. Aspiration ceases due to blockage, but the portions of the fibrin sheath drawn into the slit and into the adjoining lumen are even more difficult to expel by a reversal of the pressure differential than is a captured portion of the intimal layer of a surrounding vein. Should the application of positive pressure to a lumen blocked by the aspiration of fibrin sheath components be successful, then a substantial quantity of fibrin sheath debris is set floating throughout the cardiovascular system, and the risk is increased that the fibrin sheath will shear at the slit, permitting any portion of the fibrin sheath extending distally of the slit to also circulate as floating debris.

Elaborate structural arrangements have been proposed in response to these difficulties encountered during the aspiration and infusion of fluid through a slit in the circumferential outer wall of a vascular access catheter.

It has been suggested, for example, to enlarge portions of the exterior profile of the circumferential outer wall of the catheter in the vicinity of any slit, creating transverse

protrusions outwardly from the catheter tube in the vicinity of the slit. Such transverse protrusions, it is asserted, preclude the slit from coming into contact with the wall of the surrounding vein, or possibly with any encircling fibrin sheath, maintaining the ability to aspirate.

Transverse protrusions are, however, contrary to the generally accepted goal of holding to a minimum the size of the cross section of the exterior of any catheter tube intended for long-term residency in the cardiovascular system. Protrusions impede the easy advancement of a catheter tube along passageways of the cardiovascular system during implantation, and protrusions obstruct the flow of blood past the catheter tube, between the exterior of the catheter tube and the inner wall of the blood vessel in which the catheter tube is disposed.

An alternative approach proposed to combating problems during aspiration has been to recess a region of the circumferential outer wall of a catheter tube and to form a slit through the recessed region. A recessed region in the outer wall of a catheter tube tends to reduce the ability of a catheter tube in the vicinity of the recessed region to maintain the intended configuration of the cross section of the catheter tube. Kinking of the catheter tube at the slit, as well as lumen collapse during aspiration, are thus increased risks. In addition, a recessed region in the circumferential outer wall of a catheter tube correspondingly results in a constriction of the transverse cross section of the lumen inside the outer wall. This negatively reduces the rates of fluid flow attainable using the catheter.

Noting that the material nature and the size of the circumferential outer wall of a catheter tube can be modified to facilitate successful slit operation, attempts have been undertaken to form slits in regions of catheter tubing made from materials having physical

properties that differ from those of the balance of the catheter tube. Such efforts not only require complex manufacturing procedures, but also either increase the outer profile of the catheter tube, or constrict the size of the lumen therein.

Accordingly, the promise extended by slit valve technology continues to invite full realization.

SUMMARY OF THE INVENTION

Accordingly, it is a broad object of the present invention to increase the reliability and to reduce the costs associated with the maintenance of indwelling medical catheters. In this regard, the present invention is intended to improve patient health and to reduce the expense of medical care.

With more particularity, it is an object of the present invention to advance the design of slit structures for use as valves in medical catheters.

Another object of the present invention is to produce a catheter that uses a slit as a valve and that is capable of maintaining the configuration of the cross section of the catheter in the vicinity of the slit.

An additional object of the present invention is to minimize or eliminate the risks arising from dead space stagnation in a lumen distal of a slit used as a valve.

Still another object of the present invention is to reduce the extent of loose floating debris in the cardiovascular system produced as a result of the operation of a catheter with a slit used as a valve.

Yet another object of the present invention is a vascular access catheter that benefits from a refined slit valve design, but that avoids correspondingly increasing the size of the exterior profile of the catheter employing that design.

Relatedly, it is an object of the present invention to provide a catheter as described above without reducing the capacity to maintain the catheter cross section in the vicinity of the slit and without constricting the size of the lumen accessed through the slit.

It is further an object of the present invention to reduce damage to the intimal layer of the wall of a blood vessel occupied by a venous access catheter with a slit used as a valve.

An additional object of the present invention is to reduce the adverse interactions between a venous access catheter with a slit used as a valve and any fibrin sheath encircling that catheter in the vicinity of the slit. In light thereof, it is a related object of the present invention to minimize loose floating debris from such a fibrin sheath produced as a result of the operation of the slit as a valve.

Relatedly, it is yet another object of the present invention to minimize the adverse effects of such fibrin sheaths on the reliability of aspiration in a venous catheter with a slit used as a valve.

Cumulatively, the objects of the present invention mentioned above contribute generally to increasing the long-term reliability and minimizing the long-term injury to a patient from an implanted medical catheter.

Additional objects and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The objects and advantages of the invention may be realized and

obtained by means of the instruments and combinations particularly pointed out in the appended claims.

To achieve the foregoing objects, and in accordance with the invention as embodied and broadly described herein, a catheter is provided that includes a flexible catheter tube with a smoothly continuous outer surface that encloses a lumen defined by a smoothly continuous inner surface of the catheter tube. A terminal endwall of flexible material closes the distal end of the lumen, and a slit with opposed abutting faces is formed through the terminal endwall. The catheter tube and terminal endwall are a closed-ended fluid conduit, and the slit in the terminal endwall enables valving of the lumen to occur relative to the exterior of the distal end of the catheter tube.

According to an aspect of the present invention, a slit formed through the terminal endwall of a catheter performs the function of effecting fluid flow through a region of the lumen in the catheter tube of the device that is located immediately adjacent to the terminal endwall. The class of structures exemplified by a slit formed according to teachings of the present invention through a terminal endwall closing the otherwise open distal end of a catheter tube having smoothly continuous outer and inner surfaces will hereinafter be referred to as a selectively operable stagnation suppression means for performing that function. A slit formed in the endwall of such a catheter device and capable of performing the function of a selectively operable stagnation suppression means according to teaching of the present invention may, however, individually assume a wide variety of configurations.

Further, according to teachings of the present invention, the endwall in combination with the slit performs three functions. First, the endwall and slit together perform the function

of closing the distal end of the lumen in the catheter tube. Second, however, the slit and endwall together perform the function of infusing fluid from the lumen into the exterior of the catheter tube in a direction that is generally aligned with the longitudinal axis of the distal end of the catheter tube, whenever a predetermined positive pressure differential exists between the distal end of the lumen and the exterior of the catheter tube. Third, the endwall and slit together also perform the function of aspirating a fluid from the exterior of the catheter tube into the lumen, whenever a predetermined negative pressure differential exists between the distal end of the lumen and the exterior of the catheter tube.

The class of structures exemplified by the combination of an endwall and a slit configured according to teachings of the present invention will hereinafter be referred to as a selectively operable fluid transport means for performing those three functions. An endwall and an associated slit capable of performing the three functions of a selectively operable fluid transport means according to the teachings of the present invention may, however, individually assume a wide variety of configurations.

In the alternative to being configured as a closed-ended fluid conduit, a catheter incorporating teachings of the present invention can be configured as a flexible catheter tube with a hollow distal extension that includes an outer wall and a fluid passageway defined by an inner surface of the outer wall. The proximal end of the distal extension is secured to the distal end of the catheter tube. The configuration of the fluid passageway of the distal extension is substantially the same as the configuration of the lumen of the catheter tube where the two structures are joined. Thus, the inner surface of the proximal end of the distal extension is smoothly continuous with the inner surface of the distal end of the catheter tube.

A terminal endwall is continuously supported by the outer wall of the distal extension at the end of the distal extension opposite from the catheter tube, thus closing the distal end of the fluid passageway in the distal extension. A slit extends through the endwall of the distal extension to the fluid passageway. The slit in combination with the endwall performs the three functions of a selectively operable fluid transport means according to teachings of the present invention.

According to an aspect of the present invention, the configuration of the transverse cross section of the exterior of the proximal end of the distal extension is identical to the configuration of the transverse cross section of the exterior of the catheter tube, whereby the outer surface of the catheter tube is smoothly continuous with the outer surface of the distal extension where the two structures are joined.

Terminal endwalls of the present invention are either perpendicular to or inclined relative to the longitudinal axis of the distal extension or of the catheter tube at the terminal endwall. The orientation of a terminal endwall is best quantified with geometric specificity by reference to a plane of the endwall that is defined by the intersection of the terminal endwall with the outer wall of the distal extension or of the catheter tube. Where an endwall is inclined, the plane of the endwall forms an acute orientation angle with the longitudinal axis of the distal extension or of the catheter tube.

Terminal endwalls of the present invention are planar or convex. The thickness of such an endwall is the distance between the outer and inner surfaces of the endwall at each point thereon. The thickness of the endwall can be uniform or nonuniform, without departing from the teachings of the present invention. The outer surface of the endwall is planar, arcuate, or

semispherical. Independently thereof, the inner surface of the endwall is conical, spherical, arcuate, or planar. If the thickness of the endwall is nonuniform, that thickness may vary irregularly, or in a circularly symmetric manner about some point on the endwall, such as, but not limited to, the intersection with the endwall of the longitudinal axis of the distal extension or of the catheter tube. Depending upon the configurations and relative orientation of the outer and inner surfaces of the endwall, the endwall is thickest at a central region, at a location offset therefrom, or at the periphery of the endwall.

Slits embodying teachings of the present invention intersect the longitudinal axis of the distal extension or are offset therefrom in the direction of the periphery of the endwall. A slit may or may not be linear and may or may not extend to and through the periphery of the endwall. In some instances, the slit is among a pair or other plurality of intersecting slits formed through the endwall.

The size of the fluid passageway in the distal extension may be unchanging along the full length of the distal extension. Alternatively, the area of the fluid passageway in a transverse cross section of the proximal end of the distal extension may be less than the area of the fluid passageway in a transverse cross section of the end of the distal extension remote from the catheter tube. Under these circumstances, if the outer profile of the distal extension is uniform along the full length thereof, the outer wall of the distal extension at the terminal endwall is thinner than the outer wall of the distal extension proximal therefrom.

The principles of the present invention are applicable to single lumen catheters, as well as to catheter devices that include a pair of longitudinally extending fluid flow lumens.

Dual lumen catheter devices incorporating teachings of the present invention are configured as dual lumen closed-ended fluid conduits with terminal endwalls, or as dual lumen catheter tubes with a corresponding hollow distal extension. A distal extension for a dual lumen catheter tube encloses a pair of fluid passageways corresponding in size and configuration to respective of the lumens of the catheter tube. The lumens in a dual lumen catheter tube are separated by a septum. Thus, the distal extension for a dual lumen catheter tube includes an interior wall that corresponds and is attached to the distal end of that septum.

One or both fluid passageways of the distal extension is provided with structures capable of performing the three functions described above of a selectively operable fluid transport means according to teachings of the present invention. The distal end of each fluid passageway to which those teachings are applied is closed by a terminal endwall with a slit formed therethrough.

Terminal endwalls of this type are either perpendicular to or inclined relative to the longitudinal axis of the distal extension or of the catheter tube at the terminal endwall. The orientation of a terminal endwall in a dual lumen catheter is best quantified with geometric specificity by reference to a plane of the endwall that is defined by the intersection of the periphery of the endwall with the combination of the interior wall of the distal extension and the portion of the outer wall of the distal extension adjacent thereto. Where an endwall is inclined, the plane of the endwall forms an acute orientation angle with the longitudinal axis of the distal extension or of the catheter tube at the terminal endwall. Individual terminal endwalls may be configured as a single unified structure, thereby sharing elements, such as outer or inner

surfaces, or geometric properties, such as thickness, inclination, or curvature characteristics. Typically such individual terminal endwalls are coplanar.

Otherwise, the individual endwalls in a dual lumen catheter device are parallel, intersecting, or skewed. Intersecting endwalls most typically meet at the interior wall of the distal extension. Parallel and skewed endwalls do not meet, but encounter the interior wall of the distal extension at different locations along the length thereof and are thus longitudinally offset at the distal end of the device. The angle between the interior wall of a distal extension and each individual endwall in a dual lumen catheter device are equal or unequal.

The orientation of a slit formed through an individual endwall in a dual lumen catheter device is not restricted by teachings of the present invention. Such a slit may, accordingly, be oriented perpendicular to, parallel to, or at an acute angle to the interior wall of the distal extension, or to any given peripheral edge of the endwall.

In single lumen and dual lumen catheter devices, the length of a slit according to teachings of the present invention is adjusted in combination with the physical parameters of the endwall in which the slit is formed toward the end of meeting performance objectives predetermined for the catheter device.

The principles of the present invention also have applicability to catheter devices having more than two longitudinally extending fluid flow lumens.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described

above will be rendered by reference to a specific embodiment thereof which is illustrated in the appended drawings. Understanding that these drawings depict only a typical embodiment of the invention and are not therefore to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is a perspective view of a first embodiment of a single lumen catheter incorporating teachings of the present invention implanted in the body of a patient and accessible for the purpose of performing medical procedures through a coupling hub attached to the proximal end of the extracorporeal portion of the implanted catheter;

Figure 2 is an enlarged perspective view of the distal portion of the catheter shown in Figure 1;

Figure 3 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 2 taken along section line 3-3 shown therein;

Figure 4A is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 2 taken along section line 4-4 shown therein;

Figure 4B is the distal portion of the catheter shown in Figure 4A with the valve in the endwall thereof opened outwardly of the illustrated catheter, as when infusing fluid from the lumen of the catheter into the environment exterior thereof;

Figure 4C is the distal portion of the catheter shown in Figure 4A with the valve in the endwall thereof opened inwardly of the illustrated catheter, as when aspirating fluid from the exterior of the catheter into the lumen thereof;

Figures 5A-5E are steps in a method for manufacturing the distal portion of the catheter illustrated in Figures 1-4C;

Figure 6 is a perspective view of the distal portion of a second embodiment of a single lumen catheter incorporating teachings of the present invention;

Figure 7 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 6 taken along section line 7-7 shown therein;

Figure 8 is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 6 taken along section line 8-8 shown therein;

Figures 9A-9E are steps in a method for manufacturing the distal portion of the catheter illustrated in Figures 6-8;

Figure 10 is a longitudinal elevation view in cross section of the distal portion a third embodiment of a single lumen catheter incorporating teachings of the present invention and having an external appearance substantially similar to that of the catheter illustrated in Figure 2;

Figure 11A is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 10 taken along section line 11-11 shown therein;

Figure 11B is the distal portion of the catheter shown in Figure 11A with the valve in the endwall thereof opened outwardly of the illustrated catheter, as when infusing fluid from the lumen of the catheter into the environment exterior thereof;

Figure 11C is the distal portion of the catheter shown in Figure 11A with the valve in the endwall thereof opening inwardly of the illustrated catheter, as when aspirating fluid from the exterior of the catheter into the lumen thereof;

Figures 12A-12E are steps in a method for manufacturing the distal portion of the catheter illustrated in Figures 10-11C;

Figure 13 is a perspective view of the distal portion of a fourth embodiment of a single lumen catheter incorporating teachings of the present invention;

Figure 14 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 13 taken along section line 14-14 shown therein;

Figure 15 is a longitudinal elevation view in cross section of a fifth embodiment of a single lumen catheter incorporating teachings of the present invention and having an external appearance similar in respects to that of the catheter illustrated in Figure 13;

Figure 16 is a perspective view of the distal portion of a sixth embodiment of a single lumen catheter incorporating teachings of the present invention;

Figure 17 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 16 taken along section line 17-17 shown therein;

Figure 18 is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 16 taken along section line 18-18 shown therein;

Figure 19 is a perspective view of a seventh embodiment of a single lumen catheter embodying teachings of the present invention implanted in the body of a patient and accessible transcutaneously for the purpose of performing medical procedures through an implanted single reservoir vascular access port secured to the proximal end of the implanted catheter;

Figure 20 is an enlarged perspective view of the distal portion of the catheter shown in Figure 19;

Figure 21 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 20 taken along section line 21-21 shown therein;

Figures 22A-22G are steps in a method for manufacturing the distal portion of the catheter illustrated in Figures 19-21;

Figure 23 is an enlarged perspective view of the distal portion of an eighth embodiment of a single lumen catheter incorporating teachings of the present invention;

Figure 24 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 23 taken along section line 24-24 shown therein;

Figure 25A is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 23 taken along section line 25-25 shown therein;

Figure 25B is the distal portion of the catheter shown in Figure 25A with the valve in the endwall thereof opened outwardly of the illustrated catheter, as when infusing fluid from the lumen of the catheter into the environment exterior thereof;

Figure 25C is the distal portion of the catheter shown in Figure 25A with the valve in the endwall thereof opened inwardly of the illustrated catheter, as when aspiring fluid from the exterior of the catheter into the lumen thereof;

Figure 26 is a perspective view of the distal portion of a ninth embodiment of a single lumen catheter incorporating teachings of the present invention and having an external appearance similar in respects to that of the catheter illustrated in Figure 16;

Figure 27 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 26 taken along section line 27-27 shown therein;

Figure 28 is a perspective view of the distal portion of a tenth embodiment of a single lumen catheter incorporating teachings of the present invention;

Figure 29 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 28 taken along section line 29-29 shown therein;

Figure 30 is a longitudinal elevation view in cross section of the distal portion of an eleventh embodiment of a single lumen catheter incorporating teachings of the present invention and having an external appearance similar in respects to that of the catheter illustrated in Figure 28;

Figure 31 is a perspective view of the distal portion of a twelfth embodiment of a single lumen catheter incorporating teachings of the present invention and having an external appearance similar in respects to that of the catheter illustrated in Figure 28;

Figure 32 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 31 taken along section line 32-32 shown therein;

Figure 33 is a perspective view of a first embodiment of a dual lumen catheter embodying teachings of the present invention implanted in the body of a patient and accessible transcutaneously for the purpose of performing medical procedures through an implanted dual reservoir vascular access port secured to the proximal end of the implanted catheter;

Figure 34 is a transverse view in cross section of the catheter of Figure 33 taken along section line 34-34 shown therein;

Figure 35 is an enlarged perspective view of the distal portion of the catheter shown in Figure 34;

Figure 36 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 35 taken along section line 36-36 shown therein;

Figure 37 is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 35 taken along section line 37-37 shown therein;

Figure 38 is an enlarged perspective view of the distal portion of the catheter illustrated in Figure 35 depicting various possible orientations and positions on the endwall thereof for a slit intended to be used as a valve;

Figure 39 is a perspective view of the distal portion of a second embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 40 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 39 taken along section line 40-40 shown therein;

Figure 41 is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 39 taken along section line 41-41 shown therein;

Figure 42 is a perspective view of the distal portion of a third embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 43 is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 42 taken along section line 43-43 shown therein;

Figure 44 is a perspective view of the distal portion of a fourth embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 45 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 44 taken along section line 45-45 shown therein;

Figure 46 is a longitudinal plan view in cross section of the distal portion of the catheter illustrated in Figure 44 taken along section line 46-46 shown therein;

Figure 47 is an enlarged perspective view of the distal portion of the catheter shown in Figure 44 depicting various possible orientations and positions on the endwall thereof for a slit intended to be used as a valve;

Figure 48 is a perspective view of the distal portion of a fifth embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 49 is a perspective view of the distal portion of a sixth embodiment of a dual lumen catheter incorporating teaching of the present invention;

Figure 50 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 49 taken along section line 50-50 shown therein;

Figure 51 is an enlarged plan view of the distal portion of the catheter shown in Figure 49 depicting various possible orientations and positions on the upper of the endwalls therein for a slit intended to be used as a valve;

Figure 52 is a perspective view of the distal portion of a seventh embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 53 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 52 taken along section line 53-53 shown therein;

Figure 54 is a perspective view of the distal portion of an eighth embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 55 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 54 taken along section line 55-55 shown therein;

Figure 56 is a perspective view of the distal portion of a ninth embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 57 is a longitudinal elevation view in cross section of the distal portion of the catheter illustrated in Figure 56 taken along section line 57-57 shown therein;

Figure 58 is a longitudinal elevation view in cross section of a tenth embodiment of a dual lumen catheter incorporating teachings of the present invention;

Figure 59 is perspective view of the distal tip of a first embodiment of a triple lumen catheter incorporating teachings of the present invention;

Figure 60 is a transverse view in cross section of the catheter of Figure 59 taken along section line 60-60 shown therein;

Figure 61 is a perspective view of the distal portion of a second embodiment of a triple lumen catheter incorporating teachings of the present invention; and

Figure 62 is a transverse view in cross section of the catheter of Figure 61 taken along section line 62-62 shown therein.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 depicts a patient 10 for whom a therapeutic procedure is to be undertaken on an intermittent basis in the superior vena cava 12 of the venous subsystem of the cardiovascular system. The required access to superior vena cava 12 is provided through the implantation of a catheter device 13 that includes a soft, biocompatible, single lumen vascular access catheter tube 14 having a distal portion 16 that is intended to reside in superior vena cava 12 and that incorporates teachings of the present invention. The proximal end 18 of catheter tube 14 exits

the cardiovascular system and passes through the skin of patient 10 to the exterior of the body thereof in the vicinity of shoulder 20. Proximal end 18 of catheter tube 14 terminates in a luer connector 22 that can be selectively coupled to extracorporeal medical equipment.

Figure 2 is an enlarged perspective view of distal portion 16 of catheter tube 14 shown in Figure 1. Catheter tube 14 at distal portion 16 thereof is seen to have a longitudinal axis L_{16} and a closed distal tip 24. Distal tip 24 of catheter tube 14 includes a cylindrical circumferential outer wall 26 and a planar terminal endwall 28 that is continuously supported by outer wall 26. The periphery 30 of endwall 28 is also located on outer wall 26, whereby periphery 30 of endwall 28 is the intersection of the exterior surface of each. Periphery 30 of endwall 28 is a circle that defines a plane P_{28} of endwall 28. Plane P_{28} is perpendicular to longitudinal axis L_{16} of catheter tube 14 at distal portion 16 thereof. Extending diametrically across substantially the full extent of endwall 28 is the visible outer edge of a linear slit 32.

According to an aspect of the present invention, a catheter tube having a single longitudinally extending fluid flow lumen and a distal end closed by a terminal endwall is provided with selectively operable stagnation suppression means that performs the function of effecting fluid flow through a region of the lumen in the catheter tube immediately adjacent the terminal endwall, doing so only in response to predetermined positive and negative pressure differentials between the lumen and the exterior of the catheter tube. Slit 32 in endwall 28 shown in Figure 2 is an example of structure capable of performing this function of a selectively operable stagnation suppression means according to the teachings of the present invention.

According to another aspect of the present invention, a catheter tube having a single longitudinally extending fluid flow lumen and a closed distal end is provided with selectively

operable fluid transport means that performs three functions. First, a fluid transport means according to the teachings of the present invention functions to close the distal end of the lumen of the catheter on a selective basis. Second, the fluid transport means functions to infuse a fluid from the lumen of the catheter in a direction generally aligned with the longitudinal axis of the distal portion of the catheter, when a predetermined positive pressure differential exists between the lumen and the exterior of the distal portion of the catheter. Finally, the fluid transport means functions to aspirate fluid from the exterior of the catheter into the lumen thereof, when a predetermined negative pressure differential exists between the lumen and the exterior of the distal portion of the catheter. Slit 32 in endwall 28 shown in Figure 2 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to the teachings of the present invention.

In the elevation cross section view of distal portion 16 of catheter tube 14 presented in Figure 3, it can be seen that catheter tube 14 is a closed-ended fluid conduit that forms a longitudinally extending fluid flow lumen 34 defined by the inner surface 36 of outer wall 26 of catheter tube 14. As shown by way of illustration and not limitation, endwall 28 extends across the otherwise open distal end of lumen 34 and is continuously supported by the annular distal surface 38 of outer wall 26. Endwall 28 is secured to distal surface 38 of outer wall 26 by any of a number of appropriate methods, several of which will be disclosed subsequently.

As endwall 28 is formed separately from catheter tube 14, the material properties of endwall 28 need not be identical to those of outer wall 26 of catheter tube 14. As illustrated in Figure 3, for example, the thickness T_{28} of endwall 28 is reduced relative to the thickness T_{26} of outer wall 26 of catheter tube 14. Endwall 28 can also be made of a material having

properties of softness, tensile strength, resiliency, and even radiopacity, that contrast with the corresponding properties of the material of outer wall 26 of catheter tube 14. As a result, the behavior of endwall 28 under the influence of positive and negative pressure differentials between lumen 34 and the exterior of distal portion 16 of catheter tube 14 is, according to teachings of the present invention, rendered independent of the behavior of outer wall 26 of catheter tube 14 in response to similar positive and negative pressure differentials.

Slit 32 extends through endwall 28 between outer surface 40 and inner surface 42 thereof. Slit 32 intersects longitudinal axis L_{16} of distal portion 16 of catheter tube 14 and is contained in the plane associated with section line 3-3 shown in Figure 2. Accordingly, the elevation cross section view in Figure 3 depicts only a first slit face 44 of the two opposed slit faces that are normally engaged in the closed position of slit 32 in which lumen 34 is isolated from the exterior of distal portion 16 of catheter tube 14.

Slit face 44 is substantially rectangular in configuration, being bounded along the longer dimension thereof by an outer edge 46 and an inner edge 48 that is parallel thereto. Outer edge 46 and inner edge 48 are separated by a distance equal to thickness T_{28} of endwall 28. Outer edge 46 of slit face 44 coincides with outer surface 40 of endwall 28 and is thus the only portion of slit face 44 that is, in theory, visible in Figure 2. Inner edge 48 of slit face 44 coincides with inner surface 42 of endwall 28.

At the extremes of slit face 44, the opposed ends of outer edge 46 and inner edge 48 are joined by respective slit face junctions 50, 52. It is at slit face junctions 50, 52, that the opposite ends of the slit faces of slit 32 are permanently secured together.

The distance between slit face junctions 50, 52, defines the length S_{32} of slit 32. As shown in Figure 3, length S_{32} of slit 32 is less than the diameter D_{34} of lumen 34 of catheter tube 14. If desired, length S_{32} of slit 32 can be extended until equal to diameter D_{34} of lumen 34.

Slit face junctions 50, 52, are shown in Figure 3 by way of illustration as being both parallel to each other and perpendicular to outer edge 46 of slit face 44. Nonetheless, slit face junctions 50, 52, are less likely than are outer edge 46 and inner edge 48 of slit face 44 to be truly parallel to each other. Specific desirable functional characteristics of a slit, such as slit 32 operated as a valve, may dictate that slit face junctions 50, 52, be nonparallel, or be oriented individually at equal or unequal acute or obtuse angles, respectively, relative to outer edge 46 of slit face 44.

An orthogonally oriented view in cross section of the structures illustrated in Figure 3 is presented in Figure 4A. There, slit 32 appears on edge.

From Figures 3 and 4A taken together, it is clear that providing slit 32 in endwall 28, and securing endwall 28 to distal surface 38 of outer wall 26, are accomplished at no loss in the size of the cross section of lumen 34 and at no increase in the size of the outer cross section of distal portion 16 of catheter tube 14. These are desirable features in the distal portion of any valved venous access catheter.

The series of diagrams presented in Figures 4A-4C illustrate the three positions assumable by slit 32 when operated as a valve.

In Figure 4A, slit 32 is shown in a closed position, isolating the distal end of lumen 34 from the exterior of distal portion 16 of catheter tube 14. In the closed position of slit 32, the opposed faces of slit 32, one of which is slit face 44 illustrated in Figure 3, mutually engage in

sealing contact. The material and physical parameters of endwall 28 and slit 32 therethrough are designed to maintain the closed position of slit 32 illustrated in Figure 4A over a medically predetermined desirable range of positive as well as negative pressure differentials between lumen 34 and the exterior of distal portion 16 of catheter tube14.

Figure 4B depicts the effect on slit 32 of the application of a positive pressure differential of predetermined amount between lumen 34 and the exterior of distal portion 16 of catheter tube 14. Under such conditions, the portions of endwall 28 to either side of slit 32 bulge outwardly from lumen 34, separating slit face 44 from opposed slit face 54, and producing a gap therebetween. Through the resulting gap between slit faces 44, 54, fluid from lumen 34 is infused outwardly as a fluid jet in the manner suggested by arrow X. Figure 4B thus depicts the outwardly open position of slit 32 when operated as a valve.

A fluid jet infused into the exterior of distal portion 16 of catheter tube 14 in the manner illustrated in Figure 4B is closely aligned with longitudinal axis L_{16} of distal portion 16 of catheter tube 14. Correspondingly, in most implantations of catheter tube 14, a fluid jet infused in the manner suggested by arrow X will also be in general alignment with the longitudinal axis of the vein in which distal portion 16 of catheter tube 14 resides. As a consequence, the jet of infused fluid will not directly impinge the wall of that vessel of the cardiovascular system. Debris dislodgment from the wall of the vessel as a result of the infusion of fluid through slit 32 is reduced when compared to that occurring as a result of the infusion of fluid through a slit in the circumferential outer wall of a vascular access catheter. Furthermore, fluid infused in the direction indicated by arrow X in Figure 4B does not drive distal portion 16 of catheter tube 14 laterally in an opposite direction, toward and possibly into

collision with the wall of the vessel of the cardiovascular access system in which distal portion 16 of catheter tube 14 is disposed.

If a fibrin sheath has grown along the exterior of catheter tube 14 from the venipuncture site at which catheter tube 14 enters the venous subsystem, then the salutary dynamic interactions of distal portion 16 of catheter tube 14 with the walls of the surrounding vein are improved. For reasons yet unexplained, it does not appear that the distal end of such a fibrin sheath closes upon itself, even if the fibrin sheath extends distally beyond the distal tip of an implanted venous access catheter. Accordingly, the infusion of fluid in the manner suggested by arrow X in Figure 4B will not generally lead to tearing or debridement of an encircling fibrin sheath.

Figure 4C depicts the effect on slit 32 of the application of a negative pressure differential of predetermined amount between lumen 34 and the exterior of distal portion 16 of catheter tube 14. Under such conditions, the portions of endwall 28 to either side of slit 32 bulge inwardly into lumen 34, separating slit faces 44, 54, and producing a gap therebetween. Through the resulting gap between slit faces 44, 54, fluid from the exterior of distal portion 16 of catheter tube 14 is aspirated into lumen 34 in a manner suggested by arrow Y. Figure 4C thus depicts the inwardly open position of slit 32 when operated as a valve.

Fluid aspirated into lumen 34 in the manner illustrated in Figure 4C produces a region of suction on the outside of catheter tube 14 in the vicinity of open slit 32. This region of suction arises at the outer surface of endwall 28, not on the surface of circumferential outer wall 26. Consequently, the aspiration of fluid as illustrated in Figure 4C by arrow Y minimizes the likelihood that suction will draw distal portion 16 of catheter tube 14 toward or into contact

with the wall of the vessel of the cardiovascular system in which distal portion 16 of catheter tube 14 resides.

In addition, suction created on the exterior of distal tip 24 of catheter tube 14 by the aspiration of fluid in the manner suggested by arrow Y in Figure 4C has less of a tendency to cause adverse interactions with a fibrin sheath about catheter tube 14 than is the aspiration of fluid through a slit at other locations on catheter tube 14. The problem of the blockage of slit 32 during aspiration by the intimal layer of a vein, or by portions of a fibrin sheath, is thus reduced relative to that encountered with a slit formed through the circumferential outer wall of a venous access catheter. As a result, the use of slit 32 in endwall 28 as a valve, decreases the chance of injury to the intimal layer and the likelihood of floating debris in the blood stream, while simultaneously increasing the reliability of aspiration.

It should also be noted that the position of slit 32 at the extreme distal end of lumen 34 contributes in the maximum extent possible to the elimination of stagnant regions in lumen 34 that are resistant to flushing during the use and maintenance of catheter tube 14. As a result, clotting and the growth of bacteria in lumen 34 are minimized when catheter device 13 is not in use.

Steps in a method for manufacturing a slit and endwall, such as slit 32 in endwall 28 shown in Figures 3 and 4A, are presented in the sequence of Figures 5A-5E.

A length of tubing extruded from medical grade silicone, polyurethane, or other sufficiently durable flexible material, is first cut to a desired length. Such a result is depicted in Figure 5A, where outer wall 26 of catheter tube 14 has been severed transversely to produce annular distal surface 38 of outer wall 26.

Then, as illustrated in Figure 5B, a solid cylindrical mandrel 60 is advanced along the interior of catheter tube 14 from the proximal end thereof, occupying lumen 34. The distal face 62 of mandrel 60 is positioned in flush alignment with distal surface 38 of outer wall 26 to form a common distal endwall of the assembly. The assembly of catheter tube 14 and mandrel 60 shown in Figure 5B is then placed in a mold cavity 64 between a pair of injection mold halves 66, 68 as shown in Figure 5C. The common distal endwall of the assembly is separated from the terminus 70 of mold cavity 64 by a distance that is equal to thickness T_{28} of endwall 28 shown in Figures 3 and 4A.

As illustrated in Figure 5D, a material 72 is injected into mold cavity 64, forming endwall 28. Endwall 28 becomes continuously bonded to distal surface 38 of outer wall 26 of catheter tube 14 in the process. The resulting article is removed on mandrel 60 from between mold halves 66, 68, and trimmed to remove flashing material. Then, as illustrated in Figure 5E, slit 32 is cut through endwall 28, and mandrel 60 is removed, producing a catheter device with a closed distal portion 16 and a two-way, three-position valving structure of advantageous design and function.

The positioning and the configuration of a slit formed according to teachings of the present invention in the endwall of a catheter tube need not be exclusively as depicted in Figure 2. A linear slit, such as slit 32, is relatively easy to form and is possessed of relatively predictable behavior. The positioning of a slit, such as slit 32, in a diametrical relationship to the endwall through which the slit is formed maximizes the possible length of the slit relative to the extent of the endwall. While it is commonly considered desirable to maximize the length

of a slit, such as slit 32, specific medical applications can urge that contrasting arrangements be adapted in a slit that is to be operated as a valve.

Accordingly, depicted in Figure 6 by way of example, is a second embodiment of the distal portion of a single lumen catheter tube that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to distal portion 16 of catheter tube 14 illustrated in Figure 2. In Figure 6, catheter tube 14 can be seen to have a distal portion 76 with a longitudinal axis L_{76} and a closed distal tip 78. Distal tip 78 of catheter tube 14 includes a cylindrical circumferential outer wall 26 and a planar terminal endwall 80 continuously supported by outer wall 26. The periphery 82 of endwall 80 is also located on outer wall 26, whereby periphery 82 is the intersection of the outer surface of each. Periphery 82 of endwall 80 is a circle that defines a plane P_{80} of endwall 80. Plane P_{80} is perpendicular to longitudinal axis L_{76} of catheter tube 14 at distal portion 76 thereof. A linear slit 84 having ends in close proximity to periphery 82 of endwall 80 extends across substantially the full extent of endwall 80 at a location that is radially offset from longitudinal axis L_{76} of distal portion 76.

According to an aspect of the present invention, a catheter tube having a single longitudinally extending fluid flow lumen and a distal end closed by a terminal endwall is provided with selectively operable stagnation suppression means that performs the function of effecting fluid flow through a region of the lumen in the catheter tube located immediately adjacent the terminal endwall, doing so only in response to predetermined positive and negative pressure differentials between the lumen and the exterior of the catheter tube. Slit 84 in endwall 80 shown in Figure 6 is an example of a structure that is capable of performing this function of

a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a catheter tube having a single longitudinally extending fluid flow lumen and a closed distal end is provided with selectively operable fluid transport means that performs the three functions of closing the distal end of the lumen of the catheter, of selectively infusing fluid from the lumen of the catheter in a direction generally aligned with the longitudinal axis of the distal portion of the catheter, and of selectively aspirating fluid from the exterior of the catheter into the lumen thereof. Slit 84 in endwall 80 shown in Figure 6 is an example of structure that is capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

In the elevation cross section view of distal portion 76 of catheter tube 14 presented in Figure 7, it can be seen that catheter tube 14 is a closed-ended fluid conduit that encloses a longitudinally extending fluid flow lumen 34 defined by inner surface 36 of outer wall 26 of catheter tube 14. As shown by way of illustration and not limitation, endwall 80 extends across the otherwise open distal end of lumen 34 and is continuously supported at the periphery 86 of endwall 80 by inner surface 36 of outer wall 26 immediately proximal of annular distal surface 38 thereof. Endwall 80 is secured to inner surface 36 of outer wall 26 by any of a number of appropriate methods, several of which will be disclosed subsequently.

As endwall 80 is formed separately from catheter tube 14, the material properties of endwall 80 need not be identical to those of outer wall 26 of catheter tube 14. As illustrated in Figure 7 for example, the thickness T_{80} of endwall 80 is reduced relative to thickness T_{26} of

outer wall 26 of catheter tube 14. Endwall 80 can also be made of a material having properties of softness, tensile strength, resiliency, and even radiopacity that contrast with the corresponding properties of the material of outer wall 26 of catheter tube 14. As a result, the behavior of endwall 80 under the influence of positive and negative pressure differentials between lumen 34 and the exterior of distal portion 76 of catheter tube 14 is, according to teachings of the present invention, rendered independent of the behavior of outer wall 26 of catheter tube 14 in response to similar positive and negative pressure differentials.

Slit 84 extends through endwall 80 between outer surface 88 and interior surface 90 thereof. Slit 84 does not intersect longitudinal axis L_{76} of distal portion 76 of catheter tube 14, but is radially offset therefrom toward the end of achieving specific functional characteristics in the portions of endwall 80 to each side of slit 84. For example, the larger of the portions of endwall 80 to the side of slit 84 is more sensitive to pressure differentials between lumen 34 and the exterior of distal portion 76 of catheter tube 14 than is the smaller of the portions of endwall 80 on the opposite side of slit 84.

As the elevation view of Figure 7 is taken along a section line 7-7 shown in Figure 6 that is coplanar with the opposed slit faces of slit 84, Figure 7 depicts only a first slit face 92 of the two opposed slit faces that are normally engaged in the closed position of slit 84 in which lumen 34 is isolated from the exterior of distal portion 76 of catheter tube 14.

Slit face 92 is substantially rectangular in configuration, being bounded along the longer dimension thereof by outer edge 94 and inner edge 96 that is parallel thereto. Outer edge 94 and inner edge 96 are separated by a distance equal to thickness T_{80} of endwall 80. Outer edge 94 of slit face 92 coincides with outer surface 88 of endwall 80 and is, in theory, the

only portion of slit face 92 visible in Figure 6. Inner edge 96 of slit face 92 coincides with inner surface 90 of endwall 80.

At the extremes of slit face 92, the opposed ends of outer edge 94 and inner edge 96 are joined by respective slit face junctions 98, 100. It is at slit face junctions 98, 100, that the opposite ends of the slit faces of slit 84 are permanently secured together.

The distance between slit face junctions 98, 100, defines the length S_{84} of slit 84. As shown in Figure 7, length S_{84} of slit 84 is less than diameter D_{34} of lumen 34 of catheter tube 14. Length S_{84} of slit 84 can, however, be increased by locating the ends of slit 84 closer to outer wall 26 of distal tip 78 than is shown in Figure 7. To maximize length S_{84} of slit 84, slit face junctions 98, 100, are located at inner surface 36 of outer wall 26, rather than interior of periphery 86 of endwall 80. Nonetheless, length S_{84} of slit 84 cannot be made equal to or greater than diameter D_{34} of lumen 34, unless slit 84 is configured in a nonlinear manner, or unless slit 84 is relocated in endwall 80 radially inwardly from the position thereof illustrated in Figure 6 to such an extent that slit 84 intersects longitudinal axis L_{76} of distal portion 76. Then length S_{84} of slit 84 would equal diameter D_{34} of lumen 34.

Slit face junctions 98, 100, are shown in Figure 7 by way of illustration as being both parallel to each other and perpendicular to outer edge 94 of slit face 92. Nonetheless, slit face junctions 98, 100, are less likely than are outer edge 94 and inner edge 96 of slit face 92 to be truly parallel to each other. Specific desirable functional characteristics of a slit, such as slit 84 intended to be operated as a valve, may dictate that slit face junctions 98, 100, be nonparallel or be oriented individually at equal or unequal acute or obtuse angles relative to outer edge 94 of slit face 92.

An orthogonally oriented view in cross section of the structures illustrated in Figure 7 is presented in Figure 8. There, slit 84 is seen on edge.

From Figures 7 and 8 taken together, it is clear that providing slit 84 in endwall 80, and securing endwall 80 to inner surface 36 of outer wall 26, are accomplished at no loss in the size of the cross section of lumen 34 and at no increase in the size of the outer cross section of distal portion 76 of catheter tube 14. These are desirable features in the distal portion of a valved venous access catheter.

Steps in a method for manufacturing a slit and endwall, such as slit 84 in endwall 80 shown in Figures 7 and 8, are presented in the sequence of Figures 9A-9E.

A length of tubing extruded from a medical grade silicone, polyurethane, or other sufficiently durable flexible material, is first cut to a desired length. Such a result is depicted in Figure 9A, where outer wall 26 of catheter tube 14 has been severed transversely to produce annular distal surface 38 of outer wall 26.

Then, as illustrated in Figure 9B, a solid cylindrical mandrel 60 is advanced along the interior of catheter tube 14 from the proximal end thereof, occupying almost the full length of lumen 34. Distal face 62 of mandrel 60 is maintained at a position within the distal end of lumen 34 at a distance proximal of distal surface 38 of outer wall 26 that is equal to thickness T_{80} of endwall 80 shown in Figures 7 and 8. The assembly of catheter tube 14 and mandrel 60 shown in Figure 9B is then placed in mold cavity 64 between the pair of injection molding halves 66, 68 with distal surface 38 of outer wall 26 engaging the periphery of terminus 70 of mold cavity 64. Distal face 62 of mandrel 60 is, as a result, located at a distance

from terminus 70 of mold cavity 64 that is equal to thickness T_{80} of endwall 80 shown in Figures 7 and 8.

As illustrated in Figure 9D, a material 72 is injected into mold cavity 64, forming endwall 80, which becomes continuously bonded to inner surface 36 of outer wall 26 immediately proximal of distal surface 38 of outer wall 26. The resulting article is removed on mandrel 60 from between mold halves 66, 68, and trimmed to remove flashing material. Then, as illustrated in Figure 9E, slit 84 is cut through endwall 80 along a plane offset from the center thereof, and mandrel 60 is removed, producing a catheter device with a closed distal portion 76 and a two-way, three-position valving structure of advantageous design and function.

The three positions assumable by slit 84 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32 in endwall 28. Correspondingly, the advantages of slit 84 in endwall 80 are similar to those described in relation to Figures 4A-4C.

It should be noted, however, that the attachment of an endwall, such as either endwall 28 of Figure 2 or endwall 80 of Figure 6, need not according to teachings of the present invention be effected exclusively as disclosed above relative to each respective illustrated embodiment.

Accordingly, depicted in Figure 10 by way of example, is a third embodiment of the distal portion of a single lumen catheter device 104 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to each of distal portion 16 illustrated in Figure 3 and distal portion 76 illustrated in Figure 7.

In Figure 10, catheter device 104 can be seen to include a distal portion 106 having a longitudinal axis L_{106}. Distal portion 106 includes the distal end of catheter tube 14 and a

hollow distal extension 108 therefor that is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Distal extension 108 has an outer wall 110 with an inner surface 112 that defines a fluid passageway 114 of length F_{114}. The otherwise open proximal end 116 of distal extension 108 is secured to distal surface 38 of outer wall 26 of catheter tube 14. The configuration of the transverse cross section of fluid passageway 114 at proximal end 116 of distal extension 108 is substantially the same as the configuration of the transverse cross section of lumen 34 of catheter tube 14 at distal surface 38. As a result, inner surface 36 of outer wall 26 of catheter tube 14 at distal surface 38 is smoothly continuous with inner surface 112 of outer wall 110 of distal extension 108 at proximal end 116 thereof.

In Figure 10, however, distal extension 108 can be seen to include a closed distal end 118. A planar terminal endwall 120 is continuously supported by outer wall 110 of distal extension 108 at distal end 118 thereof. The periphery 122 of endwall 120 is also part of the exterior of outer wall 110, whereby periphery 122 is the intersection of the outer surface of each. Endwall 120 is secured to outer wall 110 by any of a number of appropriate methods, which have been discussed previously or will be discussed below. Periphery 122 of endwall 120 defines a plane P_{120} that is perpendicular to longitudinal axis L_{106} of distal portion 106 at distal end 118 of distal extension 108. A linear slit 124 with ends in close proximity to inner surface 112 of outer wall 110 extends across substantially the full extent of endwall 120 at a location that intersects longitudinal axis L_{106} of distal portion 106 at distal end 118 of distal extension 108.

According to an aspect of the present invention, a single lumen catheter tube having a hollow distal extension with a closed distal end is provided with selectively operable

stagnation suppression means that performs the function thereof described in detail previously. Slit 124 in endwall 120 shown in Figure 10 is an example of a structure capable of performing this function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a hollow distal extension with a closed distal end is provided with selectively operable fluid transport means that performs the three functions thereof described in detail previously. Slit 124 in endwall 120 shown in Figure 10 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

As distal extension 108, including both outer wall 110 and endwall 120, is formed separately from catheter tube 14, the material properties of endwall 120 in particular need not be identical to those of outer wall 26 of catheter tube 14. As illustrated in Figure 10, for example, the thickness T_{120} of endwall 120 is reduced relative to the thickness T_{26} of outer wall 26 of catheter tube 14. Endwall 120, as well as outer wall 110, can each be made of a material having properties of softness, tensile strength, resiliency, and even radiopacity, that contrast with the corresponding properties of the material of outer wall 26 of catheter tube 14. As a result, the behavior of endwall 120 under the influence of positive and negative pressure differentials between fluid passageway 114 in distal extension 108 and the exterior of distal extension 108 is, according to teachings of the present invention, rendered independent of the behavior of outer wall 26 of catheter tube 14 in response to similar positive and negative pressure differentials in lumen 34 thereof.

Slit 124 extends through endwall 120 between outer surface 126 and inner surface 128 thereof. The elevation cross section view in Figure 10 depicts only a first slit face 130 of the two opposed slit faces that are normally engaged in the closed position of slit 124 in which fluid passageway 114 is isolated from the exterior of distal extension 108.

Slit face 130 is substantially rectangular in configuration, being bounded along the longer dimension thereof by outer edge 132 and inner edge 134 that is parallel thereto. Outer edge 132 of slit face 130 coincides with outer surface 126 of endwall 120, while inner edge 134 of slit face 130 coincides with inner surface 128 of endwall 120. Thus, outer edge 132 and inner edge 134 are separated by a distance equal to thickness T_{120} of endwall 120.

At the extremes of slit face 130, the opposed ends of outer edge 132 and inner edge 134 are joined by respective slit face junctions 136, 138. It is at slit face junctions 136, 138, that the opposite ends of the slit faces of slit 124 are permanently secured together.

The distance between slit face junctions 136, 138, defines the length S_{124} of slit 124. As shown in Figure 10, length S_{124} of slit 124 is less than diameter D_{34} of lumen 34 of catheter tube 14. Length S_{124} of slit 124 is increased, however, by locating the ends of slit 124 closer to outer wall 110 of distal extension 108. Length S_{124} is maximized when slit face junctions 136, 138, are positioned against inner surface 112 of outer wall 110. Then, as slit 124 in the form depicted in Figures 10 and 11A intersects longitudinal axis L_{106} of distal portion 106, length S_{124} of slit 124 will be equal to diameter D_{34} of lumen 34.

Slit face junctions 136, 138, are shown in Figure 10 by way of illustration as being both parallel to each other and perpendicular to outer edge 132 of slit face 130. Nonetheless, the orientation of slit face junctions 136, 138, may be varied in any of the manners suggested in

relation to slit face junctions 98, 100 shown in Figure 7 toward the achievement of specific intended functional characteristics in a slit, such as slit 124 when operated as a valve.

An orthogonally oriented view in cross section of the structure illustrated in Figure 10 is presented in Figure 11A. There, slit 124 appears on edge.

From Figures 10 and 11A taken together, it is clear that providing slit 124 in endwall 120, and securing endwall 120 by way of outer wall 110 of distal extension 108 to outer wall 26 of catheter tube 14, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 104 and at no increase in the size of the outer cross section of distal portion 106 of catheter device 104. These are desirable features in the distal portion of a valved venous access catheter.

The series of diagrams presented in Figures 11A-11C illustrate the three positions assumable by slit 124 when operated as a valve.

In Figure 11A, slit 124 is shown in a closed position, isolating the distal end of fluid passageway 114 from the exterior of distal extension 108. In the closed position of slit 124, the opposed faces of slit 124, one of which is slit face 130 illustrated in Figure 10, mutually engage in sealing contact. The material and physical parameters of endwall 120 and slit 124 therethrough are designed to maintain the closed position of slit 124 illustrated in Figure 11A over a medically predetermined desirable range of positive, as well as negative, pressure differentials between fluid passageway 114 and the exterior of distal extension 108.

Figure 11B depicts the effect on slit 124 of the application of a positive pressure differential of predetermined amount between fluid passageway 114 and the exterior of distal extension 108. Under such conditions, the portions of endwall 120 to either side of slit 124

bulge outwardly from fluid passageway 114, separating slit face 130 from opposed slit face 140, and producing a gap therebetween. Through the resulting gap between slit faces 130, 140, fluid from fluid passageway 114 is infused outwardly as a fluid jet in the manner suggested by arrow X. A fluid jet infused into the exterior of distal extension 108 in this manner is aligned with longitudinal axis L_{106} of distal extension 106 and is consequently advantageous in a venous access catheter for reasons like those described above in relation to the infusion of fluid through slit 32 shown in Figure 4B. Figure 11B thus depicts the outwardly open position of slit 124 when operated as a valve.

Figure 11C depicts the effect on slit 124 of the application of a negative pressure differential of predetermined amount between fluid passageway 114 and the exterior of distal extension 108. Under such conditions, the portions of endwall 120 to either side of slit 124 bulge inwardly into fluid passageway 114, separating slit faces 130, 140, and producing a gap therebetween. Through the resulting gap between slit faces 130, 140, fluid from the exterior of distal extension 108 is aspirated into fluid passageway 114 in a manner suggested by arrow Y. A fluid jet aspirated into fluid passageway 114 produces suction on outer surface 126 of endwall 120 and is consequently advantageous in a venous access catheter for reasons like those described above in relation to the aspiration of fluid through slit 32 illustrated in Figure 4C. Figure 11C thus depicts the inwardly open position of slit 124 when operated as a valve.

Steps in a method for manufacturing a slit and endwall, such as slit 124 and endwall 120 of distal extension 108, are presented in the sequence of Figures 12A-12E.

A length of tubing extruded from medical grade silicone, polyurethane, or other sufficiently durable flexible material, is first cut to a desired length. Such a result is depicted

in Figure 12A, where outer wall 26 of catheter tube 14 has been severed transversely to produce annular distal surface 38 of outer wall 26.

Then, as illustrated in Figure 12B, a solid cylindrical mandrel 60 is advanced along and out of the interior of catheter tube 14 from the proximal end thereof, through and out of catheter tube 14. Mandrel 60 completely occupies lumen 34 and extends distally beyond distal surface 38 of outer wall 26. Distal face 62 of mandrel 60 is positioned beyond distal surface 38 of outer wall 26 by a distance equal to length F_{114} of fluid passageway 114. The assembly of catheter tube 14 and mandrel 60 shown in Figure 12B is then placed in mold cavity 64 between a pair of injection mold halves 66, 68, as illustrated in Figure 12C. Distal face 62 of mandrel 60 is separated from terminus 70 of mold cavity 64 by a distance equal to thickness T_{120} of endwall 120 of distal extension 108 shown in Figures 10 and 11A.

As illustrated in Figure 12D, a material 72 is injected into mold cavity 64, forming outer wall 110 and endwall 120 of distal extension 108. Outer wall 110 of distal extension 108 becomes continuously bonded to distal surface 38 of outer wall 26 of catheter tube 14 in the process. The resulting article is removed on mandrel 60 from between mold halves 66, 68, and trimmed to remove flashing material. Then, as illustrated in Figure 12E, slit 124 is cut through endwall 120 of distal extension 108, and mandrel 60 is removed, producing a catheter device with a closed distal portion 106 and a two-way, three-position valving structure of advantageous design and function.

The positioning and configuration of a slit formed according to teachings of the present invention in the endwall of a distal extension for a catheter tube need not be exclusively as

depicted in Figures 10 and 11A-11C. A linear slit, such as slit 124, is relatively easy to form and is possessed of relatively predictable behavior.

The positioning of a slit, such as slit 124, in a diametrical relationship to the endwall through which the slit is formed maximizes the possible length of the slit relative to the extent of the endwall. It has been found desirable to maximize the length of a slit, such as slit 124, in order to optimize the ability of a valve designer to achieve predetermined medical performance objectives. Nonetheless, specific medical applications can require that contrasting arrangements be adapted in a slit that is to be operated as a valve. Accordingly, slit 124 could, for example, be positioned within endwall 120 radially offset from longitudinal axis L_{108} of distal extension 108 in a manner similar to the radially offset positioning in endwall 80 of slit 84 illustrated in Figures 6-8. Doing so would reduce length S_{124} of the resulting slit 124.

Further, the configuration of an endwall in which a slit is formed for operation as a valve need not according to teachings of the present invention be exclusively as illustrated heretofore. Accordingly, depicted in Figure 13 by way of example, is a fourth embodiment of the distal portion of a single lumen catheter device 144 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to the inventive embodiments illustrated and discussed previously.

In Figure 13, catheter device 144 can be seen to have a distal portion 146 with a longitudinal axis L_{146} and a closed distal tip 148. Distal tip 148 of catheter device 144 includes a cylindrical circumferential outer wall and a convex terminal endwall 150 continuously supported by that circumferential outer wall. The periphery 152 of endwall 150 is also located on that circumferential outer wall, whereby periphery 152 is the intersection of the outer surface

of each. Periphery 152 of endwall 150 is a circle that defines a plane P_{150} of endwall 150. Plane P_{140} is perpendicular to longitudinal axis L_{146} of distal portion 146 of catheter device 144. Extending diametrically across substantially the full extent of endwall 150 is the visible outer edge of a slit 154 that is linear when viewed along longitudinal axis L_{146} of distal portion 146, but which in other views is curved as a result of the curvature of endwall 150.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by a convex terminal endwall is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 154 in endwall 150 shown in Figure 13 is an example of structure capable of performing this function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by a convex terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 154 in endwall 150 shown in Figure 13 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

In the cross section view presented in Figure 14, distal portion 146 of catheter device 144 can be seen to include the distal end of catheter tube 14 and a hollow distal extension 158 therefor that is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Distal extension 158 has an outer wall 110 with an inner surface 112 that defines a fluid passageway 160 of length F_{160}. The otherwise open proximal

end 116 of distal extension 158 is secured to distal surface 38 of outer wall 26 of catheter tube 14. The configuration of the transverse cross section of fluid passageway 160 at proximal end 116 of distal extension 158 is identical to the configuration of the transverse cross section of lumen 34 of catheter tube 14 at distal surface 38. As a result, inner surface 36 of outer wall 26 of catheter tube 14 at distal surface 38 thereof is smoothly continuous with inner surface 112 of distal extension 158 at proximal end 116 thereof.

Distal extension 158 includes a closed distal end 118. As shown by way of illustration and not limitation, endwall 150 is an arcuate structure that extends across the otherwise open distal end 118 of distal extension 158 and is continuously supported by outer wall 110 of distal extension 158 at distal end 118 thereof. Endwall 150 is secured to outer wall 110 by any of a number of appropriate methods, which have been discussed previously or will be discussed below.

Endwall 150 has a spherical outer surface 162 generated at a radius of curvature R_{162} about a center of curvature C_{162} that is located on longitudinal axis L_{146} of distal portion 146. Inner surface 164 of endwall 150 is also a spherical surface, but a spherical surface generated at a radius of curvature R_{164} about center of curvature C_{162}. Thus, outer surface 162 is concentric with inner surface 164, and endwall 150 exhibits a radially uniform thickness T_{150} that is equal to the difference between radius of curvature R_{162} of outer surface 162 and radius of curvature R_{164} of inner surface 164.

Radius of curvature R_{164} of inner surface 164 is greater than half of diameter D_{34} of lumen 34. Accordingly, the periphery 165 of inner surface 164 of endwall 150 is a nontangential intersection with inner surface 112 of outer wall 110 of distal extension 158.

Similarly, because radius of curvature R_{162} is greater than half of outer diameter D_{14} of catheter tube 14, periphery 152 of endwall 150 is a nontangential intersection of outer surface 162 of endwall 150 with the exterior of outer wall 110 of distal extension 158.

Outer wall 110 and endwall 150 of distal extension 158 are formed separately from catheter tube 14. As a result, the material properties of endwall 150 in particular need not be identical with those of outer wall 26 of catheter tube 14. As illustrated in Figure 14, for example, the thickness T_{150} of endwall 150 is reduced relative to the thickness T_{26} of outer wall 26 of catheter tube 14. Endwall 150, as well as outer wall 110, can be made of a material having properties of softness, tensile strength, resiliency, and even radiopacity, that contrast with the corresponding properties of the material of outer wall 26 of catheter tube 14. As a result, the behavior of endwall 150 under the influence of positive and negative pressure differentials between fluid passageway 160 in distal extension 158 and the exterior of distal extension 158 is, according to teachings of the present invention, rendered independent of the behavior of outer wall 26 of catheter tube 14 in response to similar positive and negative pressure differentials in lumen 34 thereof.

Slit 154 extends through endwall 150 between outer surface 162 and inner surface 164 thereof. The elevation cross section view in Figure 14 depicts only a first slit face 166 of the two opposed slit faces that are normally engaged in the closed position of slit 154 in which fluid passageway 160 is isolated from the exterior of distal extension 158.

Slit face 166 has an elongated, curved configuration, being bounded along the longer, curved extent thereof by an arcuate outer edge 168 and an arcuate inner edge 170 that is concentric with outer edge 168. Outer edge 168 of slit face 166 coincides with outer

surface 162 of endwall 150, while inner edge 170 of slit face 166 coincides with inner surface 164 of endwall 150. Thus, outer edge 168 and inner edge 170 are separated radially relative to center of curvature C_{162} by a uniform distance equal to thickness T_{150} of endwall 150.

At the extremes of slit face 166, the opposed ends of outer edge 168 and inner edge 170 are joined by respective slit face junctions 172, 174. It is at slit face junctions 172, 174 that the opposite ends of the slit faces of slit 154 are permanently secured together.

The distance between slit face junctions 172, 174, measured concentrically with center of curvature C_{162} defines the length S_{154} of slit 154. As shown in Figure 14, length S_{154} of slit 154 is only slightly less than diameter D_{34} of lumen 34 of catheter tube 14. Length S_{154} of slit 154 can be increased by positioning the ends of slit face 166 closer to outer wall 110 of distal extension 158 than is illustrated in Figure 14. Length S_{154} of slit 154 is maximized when slit face junctions 172, 174, are located at inner surface 112 of outer wall 110. Under these circumstances, length S_{154} of slit 154 is greater than diameter D_{34} of lumen 34 in catheter tube 14, due to the curvature of endwall 150.

Thus, for a given lumen diameter, the teachings of the present invention embodied in catheter device 144 offer the particular advantage of increased length in any associated slit that is to be operated as a valve. It has been found desirable to maximize the length of a slit to be used as a valve, in order to optimize the ability of a valve designer to achieve predetermined medical performance objectives.

Slit face junctions 172, 174, are shown in Figure 14 by way of illustration as being both parallel to each other and to longitudinal axis L_{146} of distal portion 146. Nonetheless, specific desirable functional characteristics of a slit, such as slit 154 to be operated as a valve, may

dictate that slit face junctions 172, 174, be nonparallel, or be oriented individually at equal or unequal acute or obtuse angles, respectively, relative to longitudinal axis L_{146} of distal extension 146.

The provision of slit 154 in endwall 150, and the attachment of endwall 150 by way of outer wall 110 of distal extension 158 to outer wall 26 of catheter tube 14, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 144 and at no increase in the size of the outer cross section of distal portion 146 of catheter device 144. These are desirable features in the distal portion of a valved venous access catheter.

The three positions assumable by slit 154 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32 in endwall 28 and in Figures 11A-11C relative to slit 124 in endwall 120. Correspondingly, the advantages of the operation of slit 154 in endwall 150 as a valve are similar to those described in relation to Figures 4A-4C and Figure 11A-11C.

Steps in a method for manufacturing an arcuate endwall, such as endwall 150 in which to form a slit to be used as a valve, are similar to those presented in the sequence of Figures 12A-12E. To produce the structure of endwall 150, however, distal face 62 of mandrel 60 is a spherical surface generated at a radius of curvature equal to radius of curvature R_{164} about a center of curvature located on the longitudinal axis of mandrel 60. Correspondingly, terminus 70 of mold cavity 64 is a spherical surface generated at a radius of curvature equal to radius of curvature R_{162} about a center of curvature that is located on the longitudinal axis of mold cavity 64. The arcuate distal face 62 of mandrel 60 is then positioned

in mold cavity 64 at a distance equal to thickness T_{150} from arcuate terminus 70 of mold cavity 64 with the center of curvature associated with arcuate distal face 62 of mandrel 60 coinciding with the center of curvature associated with the arcuate terminus 70 of mold cavity 64. Then material 72 is injected into mold cavity 64, forming outer wall 110 and endwall 150 of distal extension 158, and securing distal extension 158 to catheter tube 14.

It should be noted, however, that the manufacture of a convex arcuate endwall, such as endwall 150 shown in Figures 13 and 14, need not according to teachings of the present invention be effected exclusively as depicted in Figures 12A-12E. For example, a convex arcuate endwall, such as endwall 150, can be manufactured as a convex arcuate endwall attached directly to distal surface 38 of outer wall 26 of catheter tube 14 using the steps of manufacturing by which endwall 28 of distal tip 24 of catheter tube14 is manufactured in the steps of the method presented in the sequence of Figures 5A-5E. Alternatively, a convex arcuate endwall, such as endwall 150, can be manufactured as a convex arcuate endwall attached directly to inner surface 36 of outer wall 26 using the steps of manufacturing by which endwall 80 of distal tip 78 of catheter tube 14 is manufactured in the steps of the method presented in the sequence of Figures 9A-9E. Thus, it is possible accordingly to teachings of the present invention to forego the resort to any intermediary structure, such as outer wall 110 of distal extension 158, in connecting and continuously supporting a convex arcuate endwall on the otherwise open distal end of a single lumen catheter tube.

Regardless of the method used to manufacture a convex arcuate endwall, such as endwall 150, the actual configuration of such a convex arcuate endwall is not limited according to the teachings of the present invention to being exclusively as depicted in Figures 13-14.

Accordingly, depicted in Figure 15 by way of example is a fifth embodiment of the distal portion of a single lumen catheter device 184 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to distal portion 146 of catheter device 144 illustrated in Figures 13-14, as well as relative to inventive embodiments disclosed previously thereof.

In Figure 15, catheter device 184 can be seen to terminate in a distal portion 186 having a longitudinal axis L_{186}. Distal portion 186 includes the distal end of catheter tube 14 and a hollow distal extension 188 attached thereto. Distal end 118 of distal extension 188 is closed by a convex arcuate endwall 190 that is continuously supported by outer wall 110 of distal extension 188 at distal end 118 thereof. Endwall 190 is secured to outer wall 110 by any of a number of appropriate methods, which have been discussed previously or will be discussed below.

Endwall 190 has a spherical outer surface 192 generated at a radius of curvature R_{192} about a center of curvature C_{192} that is located on longitudinal axis L_{186} of distal portion 186. The inner surface 194 of endwall 190 is also a spherical surface, but a spherical surface generated at a radius of curvature R_{194} smaller than radius of curvature R_{192} of outer surface 192, and about a center of curvature C_{194} that is located on longitudinal axis L_{186} distally of center of curvature C_{192} of outer surface 192.

As a result of the separation of center of curvature C_{194} of inner surface 194 and center of curvature C_{192} of outer surface 192, outer surface 192 and inner surface 194 are eccentric, and endwall 190 exhibits a nonuniform thickness. The thickness of endwall 190 varies in a circularly symmetric manner outwardly along endwall 190 about an origin O_{190} at the

intersection of longitudinal axis L_{186} with endwall 190. At origin O_{190} the thickness of endwall 190 is minimum thickness T_{190min}. The thickness of endwall 190 increases therefrom in a circularly symmetric manner about origin O_{190} radially outwardly from longitudinal axis L_{186} to a maximum thickness T_{190max} at periphery 195 of inner surface 194 of endwall 190. There, inner surface 194 intersects inner surface 112 of outer wall 110. This relative relationship between regions of maximum and minimum thickness in endwall 190 is a result of the relative positions of center of curvature C_{192} of outer surface 192 and center of curvature C_{194} of inner surface 194.

It should be noted, however, that the configuration of a convex arcuate endwall of nonuniform thickness, such as endwall 190 of Figure 15, need not according to the teachings of the present invention be effected exclusively as depicted therein.

For example, the centers of curvature for each of the outer and the inner surfaces of a convex arcuate endwall may be reversed relative to the positions thereof illustrated in Figure 15. In such an instance, the center of curvature for the outer surface is distal of the center of curvature for the inner surface, and an arcuate endwall of nonuniform thickness results that exhibits a maximum thickness on longitudinal axis L_{186} at the center of the endwall. The minimum thickness of such an arcuate endwall occurs at the periphery of the inner surface of the endwall, at the intersection of the inner surface of the endwall with the inner surface of the circumferential outer wall of the catheter device upon which the endwall is continuously supported. Even in such an embodiment, however, the variation in the thickness of the endwall is radially symmetric about an origin, such as origin O_{190}, that is located on the endwall on longitudinal axis L_{186} of distal portion 186.

While being more geometrically complex, alternative configurations of a convex arcuate endwall of varying thickness find utility in specific medical applications for venous access catheters.

For example, either the center of curvature for the outer surface or the center of curvature for the inner surface is located on longitudinal axis L_{186} of distal portion 186, while the other of these centers of curvature is located off longitudinal axis L_{186}. The line segment between such centers of curvature will intersect longitudinal axis L_{186} at the respective of the centers of curvature located thereon. The extension of that line segment in the direction of the arcuate endwall will intersect the arcuate endwall at a point that is not located on longitudinal axis L_{186}. That point will, however, define an origin about which the thickness of the endwall varies in a circularly symmetric manner radially outwardly therefrom.

In the alternative, both the center of curvature for the outer surface and the center of curvature for the inner surface are located off longitudinal axis L_{186} of distal portion 186. The line segment between such centers of curvature will be either parallel to, intersecting of, or skewed relative to longitudinal axis L_{186}. The extension of that line segment in the direction of the arcuate endwall will intersect the arcuate endwall at a point that is located on or off of longitudinal axis L_{186}, depending upon the geometry of the distal tip of the catheter device involved. That point of intersection will, however, define an origin about which the thickness of the endwall varies in a circularly symmetric manner radially outwardly therefrom.

The origin of the circularly symmetric variation of the thickness of an arcuate endwall is either a point of minimum thickness for the endwall or a point of maximum thickness therefor. If the center of curvature for the inner surface of the endwall is closer to the inner

surface of the endwall than is the center of curvature for the outer surface of the endwall, then the origin of the circularly symmetric variation of the thickness of the endwall is a point of minimum thickness. This is the situation illustrated in Figure 15. On the other hand, if the distance from the center of curvature for the outer surface of the endwall is closer to the inner surface of the endwall than is the center of curvature for the inner surface of the endwall, then the origin of the circularly symmetric variation of the thickness of the endwall is a point of maximum thickness.

In catheter device 184 illustrated in Figure 15, radius of curvature R_{194} of inner surface 194 of endwall 190 is greater than half of diameter D_{34} of lumen 34. Accordingly, periphery 195 of inner surface 194 of endwall 190 is a nontangential intersection of inner surface 194 with inner surface 112 of outer wall 110 of distal extension 188. Similarly, because radius of curvature R_{192} of outer surface 192 of endwall 190 is greater than half of outer diameter D_{14} of catheter tube 14, periphery 196 of endwall 190 is a nontangential intersection of outer surface 192 of endwall 190 with the outer surface of outer wall 110 of distal extension 188. Periphery 196 of endwall 190 is a circle that defines a plane P_{190} of endwall 190 that is perpendicular to longitudinal axis L_{186}.

Although outer wall 110 and endwall 190 of distal extension 188 are illustrated in Figure 15 as being formed separately from catheter tube 14, a convex arcuate endwall of nonuniform thickness can be secured directly to and supported by outer wall 26 of catheter tube 14 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E.

Regardless of the method used to manufacture endwall 190, the material properties of endwall 190 need not be identical to those of outer wall 26 of catheter tube 14. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

A slit 198 extends across substantially the full extent of endwall 190 at a location that intersects longitudinal axis L_{186} of distal portion 186. The ends of slit 198 are in close proximity to inner surface 112 of outer wall 110 of distal extension 188.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by an arcuate terminal endwall of nonuniform thickness is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 198 in endwall 190 shown in Figure 15 is an example of structure capable of performing this function of a selectively operable stagnation suppression means according to the teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by an arcuate terminal endwall of nonuniform thickness is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 198 in endwall 190 shown in Figure 15 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to the teachings of the present invention.

Figure 15 depicts only a first slit face 200 from among the pair of opposed slit faces that are normally engaged in the closed position of slit 198 in which fluid passageway 160 is isolated from the exterior of distal extension 188. The shape of slit face 200 is defined largely

by the configuration of the cross section of endwall 190. Thus, slit face 200 is bounded along the longer, curved dimension thereof by an arcuate outer edge 202 and an arcuate inner edge 204 that are not radially concentric. As a result, at longitudinal axis L_{186} at the center of the length of slit 198, outer edge 202 is separated from inner edge 204 by a distance equal to the minimum thickness T_{190min} of endwall 190. At the extremes of slit face 200, outer edge 202 and inner edge 204 are joined by respective slit face junctions 206, 208, at which the opposed ends of the slit faces of slit 198 are permanently secured together. At slit face junctions 206, 208, however, outer edge 202 and inner edge 204 are separated by a distance greater than minimum thickness T_{190min} of endwall 190, but less than maximum thickness T_{190max} of endwall 190 at inner surface 112 of outer wall 110 of distal extension 188.

The curved distance between slit face junctions 206, 208, defines the length S_{198} of slit 198. Positioning slit face junctions 206, 208, radially outwardly from the positions thereof illustrated in Figure 15 increases length S_{198} of slit 198, as well as the distance of the separation between outer edge 202 and inner edge 204 at slit face junctions 206, 208. When slit face junctions 206, 208 are located at the intersection of inner surface 194 of endwall 190 with inner surface 112 of outer wall 110 of distal extension 188, length S_{198} of slit 198 is maximized, and the distance of separation between outer edge 202 and inner edge 204 at slit face junctions 206, 208, is equal to maximum thickness T_{190max} of endwall 190.

The provision of slit 198 in endwall 190, and the attachment of endwall 190 by way of outer wall 110 of distal extension 188 to catheter tube 14, are accomplished at no loss in size of the cross section of the longitudinally extending fluid flow lumen within catheter device 184

and at no increase in the size of the outer cross section of distal portion 186 of catheter device 184. These are favorable features in the distal portion of a valved venous access catheter.

The three positions assumable by slit 198 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32 in endwall 28 and in Figures 11A-11C relative to slit 124 in endwall 120. Correspondingly, the advantages of the operation of slit 198 in endwall 190 as a valve are similar to those described in relation to each of these sets of figures.

Steps in a method for manufacturing a distal extension with an arcuate endwall of nonuniform thickness, such as endwall 190 in which to form a slit to be used as a valve, are similar to those presented in the sequence of Figures 12A-12E. To produce the structure of endwall 190, however, distal face 62 of mandrel 60 is a spherical surface generated at a radius of curvature equal to radius of curvature R_{194} of inner wall 194 about a center of curvature located on the longitudinal axis of mandrel 60. Correspondingly, terminus 70 of mold cavity 64 is a spherical surface generated at a radius of curvature equal to radius of curvature R_{192} of outer surface 192 about a center of curvature located on the longitudinal axis of mold cavity 64. The arcuate distal face 62 of mandrel 60 is positioned in mold cavity 64 at a distance equal to minimum thickness T_{190min} from arcuate terminus 70 of mold cavity 64, with the center of curvature of arcuate terminus 70 located distally of the center of curvature of arcuate distal face 62. Then material 72 is injected into mold cavity 64, producing outer wall 110 and endwall 190 of distal extension 188, and securing distal extension 188 to catheter tube 14.

It should be noted, however, that the manufacture of a catheter device having a convex arcuate endwall of nonuniform thickness, such as endwall 190 of Figure 15, need not according to teachings of the present invention be effected exclusively as depicted in Figures 12A-12E.

A convex arcuate endwall of nonuniform thickness, such as endwall 190, can be attached directly to outer wall 26 of catheter tube 14 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E. Thus, it is possible according to teachings of the present invention to forego resort to any intermediary structure, such as outer wall 110 of distal extension 188, in connecting and continuously supporting a convex arcuate endwall of nonuniform thickness on the otherwise open distal end of a single lumen catheter tube.

Regardless of the method used to manufacture a convex endwall of nonuniform thickness, such as endwall 190, the actual configuration of a convex arcuate endwall of nonuniform thickness is not limited according to the teaching of the present invention to being exclusively as depicted in Figure 15.

Accordingly, depicted in Figures 16-17 by way of example is a sixth embodiment of the distal portion of a catheter device 214 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to distal portion 186 of catheter device 184 illustrated in Figure 15, as well as relative to inventive embodiments disclosed previously thereof.

In Figure 16, catheter device 214 can be seen to have a distal portion 216 with a longitudinal axis L_{216} and a closed distal tip 218. Distal tip 218 of catheter device 214 includes a cylindrical circumferential outer wall and a convex terminal endwall 220 continuously supported by that circumferential outer wall. Endwall 220 is configured with a spherical outer surface 222 having a radius of curvature equal to the radius of curvature of that cylindrical circumferential outer wall. Accordingly, the intersection of outer surface 222 of endwall 220

with the outer surface of the cylindrical circumferential outer wall of distal tip 218 is a smoothly continuous merger of surfaces. Extending diametrically across substantially the full extent of endwall 220 is the visible outer edge of a slit 224 that is linear when viewed along longitudinal axis L_{216} of distal portion 216, but which in other views is curved as a result of the curvature of endwall 220.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by an arcuate terminal endwall is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 224 in endwall 220 shown in Figures 16-18 is an example of structure capable of performing this function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by an arcuate terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 224 in endwall 220 shown in Figures 16-18 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

In the cross section view presented in Figure 17, distal portion 216 of catheter device 214 can be seen to include the distal end of catheter tube 14 and a hollow distal extension 228 therefor. The otherwise open proximal end 116 of distal extension 228 is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Inner surface 36 of outer wall 26 of catheter tube 14 at distal surface 38 thereof is smoothly

continuous with inner surface 212 of distal extension 228 at proximal end 116 thereof. Distal extension 228 has a closed distal end 118 at which endwall 220 is continuously supported by outer wall 110 and secured thereto by any of a number of appropriate methods, which have been discussed previously or will be discussed below. Outer wall 110 and endwall 220 of distal extension 228 are formed separately from catheter tube 14, advantageously permitting endwall 220 in particular to be provided with material properties relevant to the behavior of endwall 220 under the influence of positive and negative pressure differentials between fluid passageway 160 in distal extension 228 and the exterior of distal extension 228 that differ from those of catheter tube 14.

Spherical outer surface 222 of endwall 220 is generated at a radius of curvature R_{222} about a center of curvature C_{222} that is located on longitudinal axis L_{216} of distal portion 216. Endwall 220 has an inner surface 230 that is by contrast a circularly symmetric conical surface having an axis of symmetry coincident with longitudinal axis L_{216} of distal portion 216, a vertex 232, and a periphery 234 at the intersection of inner surface 230 of endwall 220 with inner surface 36 of outer wall 26 of catheter tube 14. Periphery 234 of inner surface 230 is a circle that defines a plane P_{220} of endwall 220 that is perpendicular to longitudinal axis L_{216} of distal portion 216.

The conical configuration of inner surface 230 of endwall 220 produces a nonuniform thickness in endwall 220. The combination of the disposition of center of curvature C_{222} on longitudinal axis L_{216} and the coincidence of the axis of symmetry of inner surface 230 with longitudinal axis L_{216} causes the thickness of endwall 220 to vary in a circularly symmetric manner about an origin O_{220} located on longitudinal axis L_{216}. The thickness of endwall 220 at

origin O_{220} exhibits a first local minimum corresponding to the separation along longitudinal axis L_{216} between vertex 232 of inner surface 230 and outer surface 222 of endwall 220. Radially outwardly from origin O_{220}, the thickness of endwall 220 increases to a local maximum intermediate origin O_{220} and periphery 234 of inner surface 230. Radially outwardly from that local maximum, the thickness of endwall 220 decreases to a second local minimum at periphery 234 of inner surface 230.

While inner surface 230 as illustrated in Figure 17 is radially symmetric about longitudinal axis L_{216} of distal portion 216, the configuration of the conical inner surface of an arcuate endwall of nonuniform thickness can be configured differently to achieve specific performance objectives, without detracting from the teachings of the present invention.

For example, vertex 232 of inner surface 230 may be offset from longitudinal axis L_{216} of distal portion 216. The axis of symmetry of inner surface 230 can be parallel to, intersecting of, or skewed relative to longitudinal axis L_{216} of distal portion 216. If the axis of symmetry of inner surface 230 is intersecting of or skewed relative to longitudinal axis L_{216} of distal portion 216, periphery 234 of inner surface 230 will define a plane P_{220} that is not perpendicular to longitudinal axis L_{216} of distal portion 216. Correspondingly, the axis of symmetry of inner surface 230 will intersect endwall 220 at a point that is located on or off of longitudinal axis L_{216}, depending upon the geometry of the distal tip of the catheter device involved. That point of intersection will, however, define an origin about which the thickness of the endwall varies in a circularly symmetric manner outwardly therefrom. Specific performance criteria in a catheter device may even call for a conical inner surface that is not circularly symmetric.

Figure 17 depicts only a first slit face 236 among the pair of opposed slit faces that are normally engaged in the closed position of slit 224 in which fluid passageway 160 is isolated from the exterior of distal extension 228. The shape of slit face 236 is defined by the configuration of the cross section of endwall 220. Thus, slit face 236 is bounded along the longer, curved extent thereof by a spherical outer edge 238 and an inner edge 240 made up of a pair of linear segments that meet on longitudinal axis L_{216} of distal portion 216 at vertex 232 of inner surface 230. At the extremes of slit face 236, outer edge 238 and inner edge 240 are joined by respective slit face junctions 242, 244, at which the opposed ends of the slit faces of slit 224 are permanently secured together.

The three positions assumable by slit 224 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32 in endwall 28 and in Figures 11A-11C relative to slit 124 in endwall 120. Correspondingly, the advantages of the operation of slit 224 in endwall 220 as a valve are similar to those described in relation to each of these sets of figures.

Steps in a method for manufacturing an arcuate endwall of nonuniform thickness, such as endwall 220 of distal extension 228, are similar to those presented in the sequence of Figures 12A-12E. To produce the structure of endwall 220, however, distal face 62 of mandrel 60 is a conical surface generated about the longitudinal axis of mandrel 60. Correspondingly, terminus 70 of mold cavity 64 is a spherical surface generated with a radius of curvature equal to radius of curvature R_{222} of outer surface 222 of endwall 220 about a center of curvature located on the longitudinal axis of mold cavity 64. The vertex of conical distal face 62 of mandrel 60 is positioned in mold cavity 64 at a distance from spherical terminus 70 of mold cavity 64 that is equal to the desired thickness of endwall 220 on longitudinal axis L_{216}

between vertex 232 of inner surface 230 and outer surface 222. Then material 72 is injected into mold cavity 64, producing outer wall 110 and endwall 220 of distal extension 228, and securing distal extension 228 to catheter tube 14.

It should be noted, however, that the manufacture of a catheter device having a convex endwall of nonuniform thickness, such as endwall 220 of Figures 16-18, need not according to teachings of the present invention be effected exclusively as depicted in Figures 12A-12E. For example, a convex arcuate endwall of nonuniform thickness, such as endwall 220, can be attached directly to outer wall 26 of catheter tube 14 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E. Thus, it is possible according to teachings of the present invention to forego any intermediary structure, such as outer wall 110 of distal extension 228, in connecting and continuously supporting a convex arcuate endwall of nonuniform thickness on the otherwise open end of a single lumen catheter tube.

Figure 19 depicts a patient 250 for whom a therapeutic procedure is to be undertaken on an intermittent basis in superior vena cava 12 of the venous subsystem of the cardiovascular system. The required access to superior vena cava 12 is provided through the implantation of a catheter device 254 that includes a catheter tube 14 and a distal portion 256 with a closed distal tip 258 that is intended to reside in superior vena cava 12 and that incorporates teachings of the present invention.

The proximal end 18 of catheter tube 14 exits a vein 260 of the venous subsystem of the cardiovascular system in forearm 262 of patient 250. Proximal end 18 of catheter tube 14 is attached to a vascular access port 264 that encloses a fluid reservoir accessible on a selective

basis through a needle-penetrable septum 265. Access port 264 with proximal end 18 of catheter tube 14 attached thereto is imbedded subcutaneously in the tissue of forearm 262, but outside of the cardiovascular system. To conduct a therapeutic procedure using catheter device 254, the fluid reservoir in access port 264 is accessed with the tip of a needle 266 of a hypodermic syringe 268. To do so, the tip of needle 266 is first advanced through the tissue of forearm 262 overlying access port 264 and then through needle-penetrable septum 265. Catheter device 254 in combination with access port 264 thus functions as a venous access system 269. When catheter device 254 is not in active use, syringe 268 is withdrawn, and no portion of venous access system 269 is exposed external of the body of patient 250.

Figure 20 is an enlarged perspective view of distal portion 256 of catheter device 254 shown in Figure 19. Distal portion 256 of catheter device 254 is seen to have a longitudinal axis L_{256} and a closed distal tip 258. Distal tip 258 includes a circumferential outer wall and a planar terminal endwall 270 continuously supported by that circumferential outer wall. The periphery 272 of endwall 270 is also located on that circumferential outer wall, whereby periphery 272 is the intersection of the outer surface of each. Periphery 272 of endwall 270 is a circle that defines a plane P_{270} of endwall 270. Plane P_{270} of endwall 270 is perpendicular to longitudinal axis L_{256} of distal portion 256 of catheter device 254. Extending diametrically across substantially the full extent of endwall 270 is the visible outer edge of a linear slit 274 that intersects longitudinal axis L_{256} of distal portion 256.

A thin fusion band 276 encircles the cylindrical circumferential outer wall of distal tip 258 proximal of endwall 270. Fusion band 276 is a structure produced from the use of a fusion bonding technique during the manufacture of distal portion 256 of catheter device 254.

This fusion bonding technique will be discussed subsequently in relation to the sequence of steps in the method illustrated in Figures 22A-22G.

It should be understood, however, that as illustrated in Figures 20, 21, and 22A-22G, the extent of the protrusion radially outwardly by fusion band 276 from the circumferential outer wall of distal portion 256 has been exaggerated to facilitate clear disclosure. Notwithstanding the depiction of fusion band 276 in these figures, the presence or the location in a catheter device of a fusion band, such as fusion band 276, is difficult to detect visually. Depending upon the material composition of fusion band 276 and of the other components of distal portion 256 of catheter device 254, the presence and the location of a fusion band, such as fusion band 276, might be more readily susceptible to detection tactically through the palpitation of distal portion 256 of catheter device 254.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by a planar terminal endwall is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 274 in endwall 270 in Figure 20 is an example of structure capable of performing this function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by a planar terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 274 in endwall 270 in Figure 20 is an example of structure capable of performing these

functions of a selectively operable fluid transport means according to teachings of the present invention.

In the cross section view presented in Figure 21, distal portion 256 of catheter device 254 can be seen to include the distal end of catheter tube 14, a hollow distal extension 278 therefor, and fusion band 276 by which distal extension 278 is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26.

Distal extension 278 has an outer wall 279 with an inner surface 280 that defines a fluid passageway 281 of length F_{281}. Outer wall 279 terminates in a proximal surface 282 at the otherwise open proximal end 283 of distal extension 278, where distal extension 278 is attached by way of fusion band 276 to catheter tube 14. Distal extension 278 includes a closed distal end 284. As shown by way of illustration and not limitation, endwall 270 is an extremely thin planar structure that extends across distal end 284 of distal extension 278 and is continuously supported by outer wall 279 of distal extension 278 at distal end 284 thereof. Endwall 270 is secured to outer wall 279 by any of a number of appropriate methods, which have been discussed previously or will be discussed below.

Fusion band 276 includes a centrally located bonding ring 285 that has a radially directed thickness equal to thickness T_{26} of outer wall 26 of catheter tube 14. Fusion band 276 has a longitudinally directed thickness T_{285} shown in Figure 21. A catheter tube bonding sleeve 286 extends proximally along the exterior of outer wall 26 of catheter tube 14 from the center of bonding ring 285, and an oppositely directed distal extension bonding sleeve 287 extends distally from the center of bonding ring 285 along the exterior of outer wall 279 of distal extension 278.

The opposed sides of bonding ring 285 are secured, respectively, to distal surface 38 of outer wall 26 of catheter tube 14 and to proximal surface 282 of outer wall 279 of distal extension 278. The inner surface 288 of bonding ring 285 is smoothly continuous, both with inner surface 36 of outer wall 26 of catheter tube 14, and with inner surface 280 of outer wall 279 at proximal end 283 of distal extension 278. Thus, the configuration of the transverse cross section of inner surface 288 of bonding ring 285 is identical, both to the configuration of the transverse cross section of lumen 34 of catheter tube 14 at distal surface 38, and to the configuration of the transverse cross section of fluid passageway 281 of distal extension 278 at proximal end 283 thereof.

Catheter tube bonding sleeve 286 is secured to the exterior of outer wall 26 of catheter tube 14 in the region immediately proximate of distal surface 38. Similarly, distal extension bonding sleeve 287 is secured to the outer surface of outer wall 279 of distal extension 278 in the region distal of proximal surface 282 of outer wall 279.

The radially outwardly directed protrusion of catheter tube bonding sleeve 286 and distal extension bonding sleeve 287 from the exterior of the circumferential outer wall of distal portion 256 is a maximum in a central region 290 of fusion band 276. Central region 290 of fusion band 276 thus is shown in Figure 21 and thereafter as having thickness T_{276}. According to teachings of the present invention, thickness T_{276} of fusion band 276 at central region 290 is maintained as nearly as possible to the minimum thickness required to perform the function of attaching distal extension 278 securely to catheter tube 14 in a fluid-tight relationship. Thickness T_{276} of fusion band 276 is thus extremely small, both in absolute dimensional terms and relative to the diameter D_{14} of the outer surface of catheter tube 14. Other than by securing

distal extension 278 to catheter tube 14, fusion band 276 is not intended to improve the reliability of the functioning of slit 274 when used as a valve.

Proximal of central region 290 the thickness of fusion band 276 gradually reduces in a proximal taper region 292 from thickness T_{276} of fusion band 276 at central region 290 into a smoothly continuous joinder with the exterior of outer wall 26 of catheter tube 14. Correspondingly, distal of central region 290 the thickness of fusion band 276 gradually reduces in a distal taper region 294 from thickness T_{276} of fusion band 276 at central region 290 into a smoothly continuous joinder with the exterior of outer wall 279 of distal extension 278.

In contrast to the inventive embodiments disclosed previously, the area of fluid passageway 281 in a transverse cross section of distal extension 278 at the proximal end 283 thereof is less than the area of fluid passageway 281 in a transverse cross section of distal extension 278 adjacent endwall 270 at distal end 284 of distal extension 278. Therefore, fluid passageway 281 includes an enlarged distal terminus 296 at which inner surface 280 of outer wall 279 flares radially outwardly from longitudinal axis L_{256} of distal portion 256 to form a frustoconical surface 298 that encircles distal terminus 296. The outer periphery 300 of frustoconical surface 298 takes the form of a small-radius fillet that smoothly connects frustoconical surface 298 with inner surface 302 of endwall 270. At outer periphery 300 of frustoconical surface 298, the thickness of outer wall 279 is identified in Figure 21 as a thickness T_{300}.

The transverse cross section of the exterior of outer wall 279 of distal extension 278 is unchanged along the full length thereof. Therefore, at distal terminus 296 of fluid passageway 281, frustoconical surface 298 produces a corresponding tapered wall structure 301

at distal end 284 of distal extension 278. The thickness of tapered wall structure 301 and outer wall 279 reaches a minimum at periphery 300 of frustoconical surface 298 that is equal to thickness T_{300}. Distal of periphery 300 of frustoconical surface 298, outer wall 279 of distal extension 278 increases in thickness.

The reduction in the thickness of outer wall 279 to thickness T_{300} at periphery 300 of frustoconical surface 298 correspondingly and advantageously permits the diametrical extent E_{270} of endwall 270 to be increased in direct relation to the thinning of outer wall 279 at periphery 300 of frustoconical surface 298. Accordingly, as illustrated in Figure 21, diametrical extent E_{270} of endwall 270 is larger than diameter D_{34} of lumen 34 in catheter tube 14. The thickness T_{270} of endwall 270 between inner surface 302 and outer surface 304 thereof is on the magnitude of thickness T_{300} of outer wall 279 at periphery 300 of frustoconical surface 298. Both thickness T_{270} of endwall 270 and minimum thickness T_{300} of outer wall 279 are substantially less than thickness T_{26} of outer wall 26 of catheter tube 14.

Although distal extension 278 is illustrated in Figure 21 as being formed separately from bonding ring 285, outer wall 279 can be secured directly to and supported by outer wall 26 of catheter tube 14 using the steps of the method presented in the sequence of Figures 9A-9E. Thus, proximal surface 282 of outer wall 279 of distal extension 278 can be bonded directly to distal surface 38 of outer wall 26 of catheter tube 14 without any intervening structure, such as bonding ring 285 of fusion band 276.

Regardless of the method used to manufacture catheter device 254, however, the material properties of endwall 270 need not be identical to those of outer wall 26 of catheter

tube 14. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

Slit 274 extends through endwall 270 between outer surface 304 and inner surface 302 thereof. As slit 274 intersects longitudinal axis L_{256} of distal portion 256 of catheter device 254, slit 274 is contained in the plane associated with section line 21-21 shown in Figure 20. Accordingly, the elevation cross section view in Figure 21 depicts only a first slit face 306 of the two opposed slit faces that are normally engaged in the closed position of slit 274 in which distal terminus 296 of fluid passageway 281 is isolated from the exterior of distal portion 256 of catheter device 254.

Slit face 306 is substantially rectangular in configuration, being bounded along the longer dimension thereof by an outer edge 308 and an inner edge 310 that is parallel thereto. Outer edge 308 and inner edge 310 are separated by a distance equal to thickness T_{270} of endwall 270. Outer edge 308 of slit face 306 coincides with outer surface 304 of endwall 270 and is thus the only portion of slit face 306 that is, in theory, visible in Figure 20. Inner edge 310 of slit face 306 coincides with inner surface 302 of endwall 270.

At the extremes of slit face 306, the opposed ends of outer edge 308 and inner edge 310 are joined by respective slit face junctions 312, 314. It is at slit face junctions 312, 314, that the opposite ends of the slit faces of slit 274 are permanently secured together.

The distance between slit face junctions 312, 314, defines the length S_{274} of slit 274. As shown in Figure 21, length S_{274} of slit 274 is equal to diameter D_{34} of lumen 34. Length S_{274} of slit 274 is increased through the displacement of slit face junctions 312, 314, radially outwardly along endwall 270 from the positions thereof illustrated in Figure 21. This results

in length S_{274} of slit 274 correspondingly being greater than diameter D_{34} of lumen 34, but less than diametrical extent E_{270} of endwall 270.

While slit face junctions 312, 314, are shown by way of illustration in Figure 21 as being both parallel to each other and perpendicular to outer edge 308 of slit face 306, specific desirable functional characteristics in a slit, such as slit 274 intended to be operated as a valve, may dictate that slit face junctions 312, 314, be nonparallel, or be oriented individually at equal or unequal acute or obtuse angles relative to outer edge 308 of slit face 306.

From Figure 21 it is clear that providing slit 274 in endwall 270, and securing endwall 270 to outer wall 26 of catheter tube 14 by way of outer wall 279 of distal extension 278 and bonding ring 285 of fusion band 276, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 254.

The bonding of distal extension 278 to catheter tube 14 using fusion band 276 is accomplished with only a most modest increase in the size of the outer cross section of distal portion 256 of catheter device 254 that is equal to thickness T_{276} of fusion band 276 at central region 290 thereof. Despite the appearance of fusion band 276 in Figures 20-21, thickness T_{276} thereof has been greatly exaggerated to facilitate clear disclosure. In actual practice, thickness T_{276} of fusion band 276 is relatively negligible. Accordingly, the bonding of distal extension 278 to catheter tubing 14 using fusion band 276 is accomplished at no substantial increase in the size of the outer cross section of distal portion 256 of catheter device 254.

Therefore, fusion band 276 does not impede to any significant degree the advancement of distal portion 256 of catheter device 254 along passageways of the venous system during the implantation of catheter device 254. Similarly, fusion band 276 will not in any significant way

constrict the flow of blood along the exterior of distal portion 256 of catheter device 254 between the circumferential outer wall of distal portion 256 and the wall of the vein in which distal portion 256 resides. These are desirable features in the distal portion of a valved venous access catheter.

The three positions assumable by slit 274 when operated as a valve are similar to those illustrated in Figures 4A-4C and in Figures 11A-11C. Correspondingly, the advantages of the operation of slit 274 in endwall 270 as a valve are similar to those described in relation to those figures.

Steps in a method for manufacturing a slit and endwall, such as slit 274 and endwall 270 of distal extension 256, are presented in the sequence of Figures 22A-22G.

As illustrated in Figure 22A, a solid cylindrical mandrel 320 having an outwardly flared frustoconical distal tip 322 and a planar distal face 324 is placed in a first mold cavity 326 between a first pair of injection mold halves 328, 330. Distal face 324 of mandrel 320 is separated from the terminus 332 of mold cavity 326 by a distance equal to thickness T_{270} of endwall 270 of distal extension 278 shown in Figure 21. The length of mold cavity 326 corresponds to the length of distal extension 278, which is a length equal to the sum of thickness T_{270} of endwall 270 of distal extension 278 plus length F_{281} of fluid passageway 281 of distal extension 278. The outer profile of distal tip 322 of mandrel 320 corresponds to the interior profile of distal terminus 296 of fluid passageway 281.

As illustrated in Figure 22B, a first material 334 is injected into mold cavity 326, forming outer wall 279 and endwall 270 of distal extension 278. Distal extension 278 is

removed on mandrel 320 from between mold halves 338, 340, and trimmed to remove flashing material as shown in Figure 22C.

A length of tubing extruded from medical grade silicon, polyurethane, or other sufficiently durable, flexible material is then cut to a desired length and advanced along the exterior of mandrel 320 from the end thereof opposite distal tip 322. Such a result is depicted in Figure 22D, where outer wall 26 of catheter tube 14 has been severed transversely to produce annular distal surface 38 of outer wall 26. Catheter tube 14 is positioned on mandrel 320 with distal surface 38 of outer wall 26 at a distance from proximal surface 282 of outer wall 279 of distal extension 278 that is equal to thickness T_{285} of bonding ring 285 of fusion band 276 shown in Figure 21.

The assembly of distal extension 278, mandrel 320, and catheter tube 14 shown in Figure 22D is then placed in a second mold cavity 336 between a second pair of injection mold halves 338, 340. Second mold cavity 336 encircles the assembly in the vicinity of the gap in the assembly between distal surface 38 of outer wall 26 of catheter tube 14 and proximal surface 282 of outer wall 279 of distal extension 278. The radially outermost portion of second mold cavity 336 is located at a distance from the exteriors of outer wall 26 of catheter tube 14 and outer wall 279 of distal extension 278 equal to the maximum thickness T_{276} of fusion band 276 illustrated in Figure 21.

As illustrated in Figure 22F, a second material 342 is injected into second mold cavity 336, forming bonding ring 285, catheter tube bonding sleeve 286, and distal extension bonding sleeve 287 of fusion band 276. In the process, the exterior of outer wall 26 of catheter tube 14 becomes continuously bonded to catheter tube bonding sleeve 286, while distal

surface 38 of outer wall 26 of catheter tube 14 becomes continuously bonded to bonding ring 285. Correspondingly, the exterior of outer wall 279 of distal extension 278 becomes continuously bonded to distal extension bonding sleeve 287, while proximal surface 282 of outer wall 279 of distal extension 278 becomes continuously bonded to bonding ring 285. The resulting article is catheter device 254, which is removed on mandrel 320 from between mold halves 338, 340, and trimmed to remove flashing material.

Then, as illustrated in Figure 22G, slit 274 is cut through endwall 270 of distal extension 278 to produce a catheter device with a closed distal portion 256 and a two-way, three-position valving structure of advantageous design and function.

Notwithstanding the enlarged outer diameter of distal tip 322 of mandrel 320, the material of the components of catheter device 254 are possessed of such flexibility and elasticity as to permit the removal therefrom along the longitudinally extending fluid flow lumen therein of mandrel 320. Mandrel 320 and distal tip 322 are drawn in a proximal direction out of the assembly illustrated in Figure 22G. The materials of outer wall 279 of distal extension 278, of bonding ring 285 of fusion band 276, and of outer wall 26 of catheter tube 14 yield temporarily radially outwardly to accommodate the passage of distal tip 322 of mandrel 320 therethrough. Outer wall 279, bonding ring 285, and outer wall 26 resume the original dimensions and configuration of each following the withdrawal of distal tip 322 of mandrel 320 through each, respectively.

It should be noted, however, that the manufacture of a catheter device having an endwall of enlarged diameter, such as endwall 270 of Figures 20-21, need not, according to teachings of the present invention, be effected exclusively as depicted in Figures 22A-22G. An

endwall of enlarged diameter, such as endwall 270 supported by outer wall 279 of distal extension 278, can be attached directly to distal surface 38 of outer wall 26 of catheter tube 14 using the steps of the method presented in the sequence of Figures 9A-9E. Thus, it is possible according to the teachings of the present invention to forego any intermediary structure, such as bonding ring 285 of fusion band 276, in connecting and continuously supporting an endwall of enlarged diameter on the otherwise open distal end of a single lumen catheter tube.

The positioning and configuration of a slit formed according to teachings of the present invention in the endwall of the distal extension of a catheter tube need not be exclusively as depicted in Figures 20-21. A linear slit, such as slit 274, is relatively easy to form and is possessed of relatively predictable behavior.

The positioning of a slit, such as slit 274, in a diametrical relationship to the endwall through which the slit is formed maximizes the possible length of the slit relative to the extent of the endwall. It has been found desirable to maximize the length of the slit, such as slit 274 in endwall 270, in order to optimize the ability of a valve designer to achieve any given medical performance objectives. Nonetheless, specific medical applications can require that an alternative arrangement be adopted relative to a slit that is to be operated as a valve. Accordingly, slit 274 could, for example, be positioned within endwall 270 radially offset from longitudinal axis L_{256} of distal portion 256 in a manner similar to the radially offset positioning of slit 84 in endwall 80 illustrated in Figures 6-8.

Alternatively, depicted in Figure 23 by way of example, is an eighth embodiment of the distal portion of a single lumen catheter device 344 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to the inventive

embodiments illustrated and discussed previously. Catheter device 344 is there seen to have a distal portion 346 with a longitudinal axis L_{346} and a closed distal tip 348. Distal tip 348 of catheter device 344 includes a circumferential outer wall and a planar terminal endwall 270 continuously supported by that circumferential outer wall. Extending diametrically across the full extent of endwall 270 is the visible outer edge of a slit 354 that intersects longitudinal axis L_{346} of distal portion 346 and assumes a 90-degree bend at periphery 272 of endwall 270.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by a planar terminal endwall is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 354 in endwall 270 shown in Figure 23 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by a planar terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 354 in endwall 270 shown in Figure 23 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

As appreciated by reference to the cross section view presented in Figure 24, slit 354 extends not only through endwall 270 between outer surface 304 and inner surface 302 thereof, but slit 354 extends through the exterior of distal end 284 of outer wall 279 of distal extension 278. As slit 354 intersects longitudinal axis L_{346} of distal portion 346 of catheter

device 344, slit 354 is contained in the plane associated with section line 24-24 shown in Figure 23. Accordingly, the elevation cross section view in Figure 24 depicts only a first slit face 356 of the two opposed slit faces that are normally engaged in the closed position of slit 354 in which distal terminus 296 of fluid passageway 281 is isolated from the exterior of distal portion 346 of catheter device 344.

Slit face 356 is an elongated, somewhat rectangular, C-shaped surface bounded by an outer edge 358 and an inner edge 360. Outer edge 358 includes an elongated straight central portion 362 and a pair of short end portions 364 disposed perpendicular thereto and interconnected therewith by individual rounded corner fillets 366. Central portion 362 of outer edge 358 coincides with outer surface 304 of endwall 270, while end portions 364 coincide with the exterior of distal end 284 of outer wall 279 of distal extension 278. Fillet corners 366 are thus located on periphery 272 of endwall 270. The distance between end portions 364 of outer edge 358 defines the length S_{354} of slit 354. As shown in Figure 24, length S_{354} is equal to diameter D_{14} of the exterior of catheter tube 14.

Inner edge 360 of slit face 356 includes an elongated straight central portion 368 and a terminal corner fillet 370 at each end thereof. Central portion 368 of inner edge 360 of slit face 356 coincides with inner surface 302 of endwall 270, while terminal corner fillets 370 coincide with the interior of tapered wall structure 301 at periphery 300 of frustoconical surface 298. Central portion 362 of outer edge 358 and central portion 368 of inner edge 360 are separated by a distance equal to thickness T_{270} of endwall 270.

At the extreme ends of slit face 356, the opposed ends of outer edge 358 and inner edge 360 are joined by respective slit face junctions 372, 374. It is at slit face

junctions 372, 374, that the opposed ends of the slit faces of slit 354 are permanently secured together. At slit face junctions 372, 374, outer edge 358 and inner edge 360 are separated by a distance equal to thickness T_{300} of tapered wall structure 301 at periphery 300 of frustoconical surface 298.

Slit face junctions 372, 374, are shown by way of illustration in Figure 24 as being colinear with each other and perpendicular to end portions 364 of outer edge 358 of slit face 356. Nonetheless, specific desirable functional characteristics in a slit, such as slit 354 intended to be operated as a valve, may dictate that slit face junctions 372, 374, be non-colinear, or be oriented individually at equal or unequal acute or obtuse angles relative to respective end portions 364 of outer edge 358 of slit face 356. In addition, one or both of slit face junctions 372, 374, can be positioned proximally along outer wall 279 of distal extension 278 from the positions thereof shown in Figure 24.

Although distal extension 278 is illustrated in Figure 24 as being secured directly to and supported by outer wall 26 of catheter tube 14, proximal surface 282 of outer wall 279 of distal extension 278 can in the alternative be bonded indirectly to distal surface 38 of outer wall 26 of catheter tube 14 using an intermediary structure, such as bonding ring 285 illustrated in Figures 20-21.

Regardless of the method used to manufacture catheter device 344, the material properties of endwall 270 need not be identical to those of outer wall 26 of catheter tube 14. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 24 it is clear that providing slit 354 in endwall 270, and securing endwall 270 to outer wall 26 of catheter tube 14, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 344 and at no increase in the size of the outer cross section of distal portion 346 of catheter device 344.

The series of diagrams presented in Figures 25A-25C illustrate the three positions assumable by slit 354 when operated as a valve.

An orthogonally oriented view in cross section of the structure illustrated in Figure 24 is presented in Figure 25A. There, slit 354 appears on edge in the closed position thereof, isolating the distal end of fluid passageway 281 from the exterior of distal portion 346 of catheter device 344. In the closed position of slit 354, the opposed faces of slit 354, one of which is slit face 356 illustrated in Figure 24, mutually engage in sealing contact. The material and physical parameters of endwall 270 and slit 354 are designed to maintain the closed position of slit 354 illustrated in Figure 25A over a medically predetermined desirable range of positive, as well as negative, pressure differentials between fluid passageway 281 and the exterior of distal portion 346.

Figure 25B depicts the effects on slit 354 of the application of a positive pressure differential of predetermined amount between fluid passageway 281 and the exterior of distal portion 346 of catheter device 344. Under such conditions, the portions of endwall 270 to either side of slit 354 bulge outwardly from distal terminus 296 of fluid passageway 281, separating slit face 356 from opposed slit face 376, and producing a gap therebetween. Through the resulting gap between slit faces 356, 376, fluid from fluid passageway 281 is infused outwardly as a fluid jet in the manner suggested by arrow X. A fluid jet infused into the exterior

of distal portion 346 of catheter device 344 in this manner is aligned with longitudinal axis L_{346} of distal portion 346 and is consequently advantageous in a venous access catheter for reasons like those described above in relation to the infusion of fluid through slit 32 shown in Figure 4B and slit 124 shown in Figure 11B. Figure 25B thus depicts the outwardly open position of slit 354 when operated as a valve.

Figure 25C depicts the effects on slit 354 of the application of a negative pressure differential of predetermined amount between fluid passageway 281 and the exterior of distal portion 346 of catheter device 344. Under such conditions, the portions of endwall 270 to either side of slit 354 bulge inwardly into distal terminus 296 of fluid passageway 281, separating slit faces 356, 376, and producing a gap therebetween. Through the resulting gap between slit faces 356, 376, fluid from the exterior of distal portion 346 of catheter device 344 is aspirated into fluid passageway 281 in a manner suggested by arrow Y. A fluid jet aspirated into fluid passageway 281 produces suction on outer surface 304 of endwall 270 and is consequently advantageous in a venous access catheter for reasons like those described above in relation to the aspiration of fluid through slit 32 illustrated in Figure 4C and through slit 124 illustrated in Figure 11C. Figure 25C thus depicts the inwardly open position of slit 356 when operated as a valve.

Steps in a method for manufacturing an enlarged endwall, such as endwall 270 in which to form a slit to be used as a valve, are similar to those presented in the sequence of Figures 12A-12E. It should be noted, however, that the manufacture of an endwall, such as endwall 270 in which to form a slit to be used as a valve, could also be implemented according

to the teachings of the present invention using steps similar to those of the fusion bonding method presented in the sequence of Figures 22A-22G.

Regardless of the method used to manufacture an endwall, such as endwall 270, the actual configuration of such an endwall is not limited according to the teachings of the present invention to being configured exclusively as depicted in Figures 23-24.

Accordingly, depicted by way of example in Figures 26-27 is a ninth embodiment of the distal portion of a single lumen catheter device 384 that incorporates teachings of the present invention. Although the distal portion of catheter device 384 is possessed of an overall external appearance that is similar in certain respects to that of catheter device 214 in Figure 16, the distal portion of catheter device 384 includes structural features that contrast with those of catheter device 214.

In Figure 26, catheter device 384 can be seen to have a distal portion 386 with a longitudinal axis L_{386} and a closed distal tip 387. Distal tip 387 of catheter device 384 includes a cylindrical circumferential outer wall and a convex terminal endwall 388 continuously supported by that circumferential outer wall. Endwall 388 is configured with a spherical outer surface 389 having a radius of curvature equal to the radius of curvature of that cylindrical circumferential outer wall. Accordingly, the intersection of outer surface 389 of endwall 388 with the exterior surface of the cylindrical circumferential outer wall of distal tip 387 is a smoothly continuous merger of surfaces.

Extending diametrically across substantially the full extent of endwall 388 is a pair 390 of intersecting slits 391, 392, that cross at an intersection point I_{390} located on longitudinal axis L_{386} of distal portion 386. The visible outer edges of slits 391, 392, are linear when viewed

along longitudinal axis L_{386} of distal portion 386, but are curved in other views as a result of the curvature of endwall 388. When viewed along longitudinal axis L_{386} of distal portion 386, slit 391 is perpendicular to slit 392 at intersection point I_{390}.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by a spherical terminal endwall is provided with selectively operable stagnation suppression means for performing the function thereof disclosed in detail previously. Pair 390 of slits 391, 392, shown in Figure 26 is an example of structures capable of performing this function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by a spherical terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Pair 390 of slits 391, 392, shown in Figure 26 is an example of structures capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

In the cross section view presented in Figure 27, distal portion 386 can be seen to include the distal end of catheter tube 14 and a hollow distal extension 393 therefor that is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Distal extension 393 has an outer wall 394 with an inner surface 396 that defines a fluid passageway 398 of length F_{398}. Inner surface 36 of outer wall 26 of catheter tube 14 at distal surface 38 is smoothly continuous with inner surface 396 of outer wall 394 of distal extension 393 at proximal end 400 thereof.

Although distal extension 393 is illustrated in Figure 26 as being secured directly to and supported by outer wall 26 of catheter tube 14, outer wall 394 of distal extension 393 can in the alternative be bonded indirectly to distal surface 38 of outer wall 26 of catheter tube 14 using an intermediary structure, such as bonding ring 285 illustrated in Figures 20-21.

The distal extent of fluid passageway 398 is terminated by endwall 388, which is continuously supported by distal end 402 of outer wall 394 of distal extension 393. Spherical outer surface 389 of endwall 388 is generated at a radius of curvature R_{389} about a center of curvature C_{388} located on longitudinal axis L_{386} of distal portion 386. Radius of curvature R_{389} is equal to half of diameter D_{14} of the exterior of outer wall 26 of catheter tube 14.

The inner surface 404 of endwall 388 is also a spherical surface, but a spherical surface generated at a radius of curvature R_{404} about center of curvature C_{388}. Thus, inner surface 404 is concentric with outer surface 389, and endwall 388 exhibits a radially uniform thickness T_{388} that is equal to the difference between radius of curvature R_{389} of outer surface 389 and radius of curvature R_{404} of inner surface 404.

Radius of curvature R_{404} of inner surface 404 is greater than half of diameter D_{34} of lumen 34, and inner surface 404 is greater in extent than a hemisphere. Accordingly, the periphery 406 of inner surface 404 of endwall 388 is a nontangential intersection with inner surface 396 of outer wall 394. Periphery 406 of inner surface 404 is a circle that defines a plane P_{406} that is perpendicular to longitudinal axis L_{386} of distal portion 386 at a location proximal of center of curvature C_{388} of endwall 388. As a result of the size of radius of curvature R_{404} of inner surface 404 of endwall 388 relative to diameter D_{34} of lumen 34, fluid passageway 398 includes an enlarged distal terminus 408 at which inner surface 396 of outer

wall 394 flares radially outwardly from longitudinal axis L_{386} of distal portion 386, forming proximal portion 409 of spherical inner surface 404.

The transverse cross section of the exterior of outer wall 394 of distal extension 393 is unchanged along the full length thereof. Therefore, at distal terminus 408 of fluid passageway 398, proximal portion 409 of spherical inner surface 404 produces a corresponding tapered wall structure 410 at distal end 402 of outer wall 394.

Slit 391 extends through endwall 388 between outer surface 389 and inner surface 404 thereof. Slit 391 is contained in the plane associated with section line 27-27 shown in Figure 26. Accordingly, the elevation cross section view in Figure 27 depicts only a first slit face 414 of the two opposed slit faces that are normally engaged in the closed position of slit 391 in which fluid passageway 398 is isolated from the exterior of distal extension 386. As slit 392 is perpendicular to slit 391, slit 392 appears in Figure 27 on edge at intersection point I_{390} of slit 392 with slit 391.

The shape of slit face 414 of slit 391 is defined largely by the configuration of the cross section of endwall 388. Thus, slit face 414 is bounded along the longer, curved extent thereof by an arcuate outer edge 416 and an arcuate inner edge 418 that are concentric. As a result, outer edge 416 is separated from inner edge 418 by a uniform distance equal to thickness T_{388} of endwall 388. At the extremes of slit face 414, outer edge 416 and inner edge 418 are joined by respective slit face junctions 420, 422, at which the opposed ends of the slit faces of slit 391 are permanently secured together.

The curved distance between slit face junctions 420, 422, defines the length S_{391} of slit 391. Positioning slit face junctions 420, 422, proximally from the positions thereof

illustrated in Figure 26 increases length S_{391} of slit 391. Due to the curvature in endwall 388, length S_{391} of slit 391 is greater than either diameter D_{34} of lumen 34 or diameter D_{14} of the exterior of outer wall 26 of catheter tube 14.

Slit 392, which is seen on edge in Figure 27, is configured similarly to slit 391 described in detail above. The length S_{392} of slit 392 is, of necessity, identified only in Figure 26. In the embodiment illustrated in Figures 26-27, length S_{392} of slit 392 is approximately equal to length S_{391} of slit 391. Alternative configurations are, however, within the scope of the teachings of the present invention.

Length S_{392} of slit 392 may be less than length S_{391} of slit 391 to facilitate specific performance objectives in a pair of intersecting slits, such as pair 390. Additionally, the portion of the length of a slit, such as slit 392, to either side of intersection point I_{390} need not be equal, as is the case with slit 392.

Indeed, it is within the scope of the teachings of the present invention that a pair of intersecting slits, such as pair 390, include a first slit that intersects, but does not cross, the second slit of the pair. Under these circumstances, the full extent of the first slit is disposed entirely on one side of the second slit, and the intersection point of the pair of slits is an endpoint of the first slit. If the first slit and the second slit are perpendicular to each other in the manner of slits 391, 392, illustrated in Figures 26-27, then the resulting pair of slits assumes a T-shaped configuration when viewed along the longitudinal axis of the distal end of the corresponding catheter device. The endwall on the side of the second slit occupied by the first slit is separated into a pair of similarly configured slit wall portions.

Nonetheless, according to teachings of the present invention the slits in a pair of intersecting slits, such as pair 390, need not be perpendicular to each other. The slits of such a pair may instead form pairs of supplementary angles relative to each other. Under such circumstances, the endwall on either side of each of the slits is separated by the other of the slits into slit wall portions having differing configurations. The slits in such a pair of intersecting slits can cross each other, as in the case of slits 391, 392, or intersect at an endpoint of one of the slits.

According to teachings of the present invention, it is also appropriate to configure a valve in the distal tip of a catheter device using a plurality of three or more intersecting slits. Typically, but not exclusively, any such plurality of intersecting slits will be mutually intersecting at an endpoint of each slit, whereby the individual slits of the plurality of slits extend radially outwardly from the point of mutual intersection like spokes from the hub of a wheel. In such a spoke-like configuration of a plurality of intersecting slits, each individual slit can be positioned about the common point of intersection at equal or at unequal angles, respectively, to the radially adjacent slits on either side thereof. Nevertheless, a plurality of three or more intersecting slits intended to be used as a valve need not be mutually intersecting at a single point. It is not inconsistent with the teachings of the present invention in a plurality of three or more intersecting slits for any individual slit thereof to intersect fewer than all of the other in that plurality.

From Figure 27, it is clear that providing pair 390 of slits 391, 392, in endwall 388, and attaching endwall 388 by way of outer wall 394 of distal extension 393 to catheter tube 14, are accomplished at no loss in size of the cross section of the longitudinally extending fluid flow

lumen within catheter device 384, and at no increase in the size of the outer cross section of distal portion 386 of catheter device 384. These are favorable features in the distal portion of a valved venous access catheter.

The three positions assumable by pair 390 of slits 391, 392 when operated together as a valve are similar individually to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of pair 390 of slits 391, 392, in endwall 388 when operated together as a valve are similar to those described in relation to each of these sets of figures. Nonetheless, it has been observed that the use of a pair of intersecting slits, such as pair 390, in a sharply convex end wall, such as spherical end wall 388, greatly facilitates the reliable operation of that pair of slits together as a valve for both infusion and for aspiration.

Steps in a method for manufacturing a spherical endwall of uniform thickness, such as endwall 388 in which to form one or more slits to be used as a valve, are similar to those presented in the sequence of Figures 12A-12E. It should be noted, however, that the manufacture of an endwall, such as endwall 388 in which to form a slit to be used as a valve, could also be implemented according to the teachings of the present invention using steps similar to those employing the fusion bonding technique presented in the sequence of Figures 22A-22G.

The positioning and configuration of a slit or slits formed according to the teachings of the present invention in a spherical endwall of uniform thickness need not be exclusively as depicted in Figure 26. Linear slits, such as slits 391, 392, are relatively easy to form and are possessed of relatively predictable behavior.

The positioning of the slit, such as slits 391, 392, in a diametrical relationship to a spherical endwall, such as endwall 388, maximizes the possible length of each respective slit relative to the extent of the endwall. While it has been found desirable in achieving selected medical performance objectives to maximize the length of slits, such as slits 391, 392 in endwall 388, other medical applications can require that an alternative arrangement be adopted relative to a slit or slits to be operated as a valve. Accordingly, either or both of slits 391, 392, could, for example, be positioned within endwall 388 radially offset from longitudinal axis L_{386} of distal portion 386 in a manner similar to the radially offset positioning in endwall 80 of slit 84 illustrated in Figures 6-8.

Depicted by way of example in Figure 28 is a tenth embodiment of the distal portion of a single lumen catheter device 424 that incorporates teachings of the present invention, but that includes contrasting structural characteristics relative to the inventive embodiments illustrated and disclosed previously. Catheter device 424 is there seen to have a distal portion 426 with a longitudinal axis L_{426} and a closed distal tip 428. Distal tip 428 of catheter device 424 includes a circumferential outer wall and a planar terminal endwall 430 continuously supported by that circumferential outer wall. The periphery 432 of endwall 430 is also located on the exterior of that circumferential outer wall, whereby periphery 432 is the intersection of the exterior surface of each.

Periphery 432 of endwall 430 is an ellipse having a maximum diametrical extent E_{430max} measured along the major axis of that ellipse and a minimum diametrical extent E_{430min} measured perpendicular thereto along the minor axis of that ellipse. Periphery 432 of endwall 430 defines a plane P_{430} of endwall 430 that forms an acute orientation angle A_{430} with longitudinal axis L_{426}

of distal portion 426 of catheter device 424. Thus, endwall 430 is inclined relative to longitudinal axis L_{426}. Extending diametrically across substantially the full extent of the longest dimension of endwall 430 is the visible outer edge of a linear slit 434 that intersects longitudinal axis L_{426} of distal portion 426.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by an inclined planar terminal endwall is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 434 in endwall 430 in Figure 28 is an example of structure capable of performing this function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by an inclined planar terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 434 in endwall 430 in Figure 28 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

In the cross section view presented in Figure 29, distal portion 426 of catheter device 424 can be seen to include the distal end of catheter tube 14 and a distal extension 436 therefor that is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Distal extension 436 has an outer wall 438 with an inner surface 440 that defines a fluid passageway 442 of length F_{442}. The otherwise open proximal end 444 of distal

extension 436 is attached to catheter tube 14. Distal extension 436 includes a closed distal end 446.

As shown by way of illustration and not limitation, endwall 430 is a planar structure that extends across distal end 446 of distal extension 436 and is continuously supported by outer wall 438 of distal extension 436 at distal end 446 thereof. Endwall 430 has an outer surface 448 visible but not labeled in Figure 28 and an inner surface 450 that is parallel thereto. Accordingly, endwall 430 has a thickness T_{430} equal to the distance between outer surface 448 and inner surface 450 thereof. Endwall 430 is secured to outer wall 438 by any of a number of appropriate methods, which have been discussed previously or will be discussed below.

Although distal extension 436 is illustrated in Figure 29 as being secured directly to and supported by outer wall 26 of catheter tube 14, outer wall 438 of distal extension 436 can, in the alternative, be bonded indirectly to distal surface 38 of outer wall 26 of catheter tube 14 using an intermediary structure, such as bonding ring 285 illustrated in Figures 20-21.

Regardless of the method used to manufacture catheter device 424, the material properties of endwall 430 need not be identical to those of outer wall 26 of catheter tube 14. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 29 it is clear that providing slit 434 in endwall 430, and securing endwall 430 to outer wall 26 of catheter tube 14, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 424, and at no increase in the size of the outer cross section of distal portion 426 of catheter device 424.

Figure 29 depicts only a first slit face 452 of the two opposed slit faces that are normally engaged in the closed position of slit 434 in which fluid passageway 442 is isolated from the exterior of distal extension 436. Thus, slit face 452 is bounded along the longer dimension thereof by a linear outer edge 454 and a linear inner edge 456 that is parallel thereto. As a result, outer edge 454 is separated from inner edge 456 by a distance equal to thickness T_{430} of endwall 430. At the extremes of slit face 452, outer edge 454 and inner edge 456 are joined by respective slit face junctions 458, 460, at which the opposed ends of the slit faces of slit 434 are permanently secured together.

The distance between slit face junctions 458, 460, defines the length S_{434} of slit 434. Slit face junctions 458, 460, are shown by way of illustration in Figure 29 as being parallel to each other and perpendicular to outer surface 448 of endwall 430. Nonetheless, specific desirable functional characteristics in the slit, such as slit 434 intended to be operated as a valve, may dictate that slit face junctions 458, 460, be nonparallel, or be oriented individually at equal or unequal acute or obtuse angles relative to surface 448 of endwall 430. Slit face junctions 458, 460, are positioned radially outwardly in endwall 430 to the maximum extent possible without passing through outer wall 438 of distal extension 436.

Nonetheless, specific medical applications can require that an alternative arrangement be adopted relative to a slit that is to be operated as a valve. Accordingly, slit face junctions 458, 460, could be located radially inwardly along endwall 430 from the positions thereof illustrated in Figure 28, or slit 434 could be positioned within endwall 430 radially offset from longitudinal axis L_{426} of distal portion 426 in a manner similar to the radially offset positioning in endwall 80 of slit 84 illustrated in Figures 6-8.

The three positions assumable by slit 434 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the operation of slit 434 in endwall 430 as a valve are similar to those described in relation to each of these sets of figures, with one minor qualification. A design tradeoff exists, however, between an increase in slit length arising from the inclination of the endwall through which the slit is formed and the advantageousness of the operation of the corresponding slit as a valve.

As a result of the inclination of endwall 430, a jet of fluid infused from catheter device 424 through slit 434 will not be in complete alignment with longitudinal axis L_{426} of distal portion 426. Instead, as suggested by arrow I in Figure 29, a jet of fluid infused from catheter device 424 through slit 434 will be infused in a direction that is approximately perpendicular to plane P_{430} of endwall 430. As a result, less than all of the force of such a fluid jet is in true alignment with longitudinal axis L_{426}. The fractional portion of such a fluid jet that is aligned with longitudinal axis L_{426} is equal to the sine of orientation angle A_{430}.

Correspondingly, a fractional portion of the force of such a fluid jet is oriented in a direction perpendicular to longitudinal axis L_{426}, directed at any fibrin sheath encircling distal tip 428 of catheter device 424, or at the interior of the walls of the vein in which distal portion 426 of catheter device 424 is disposed. The fractional portion of the force of such a fluid jet that is oriented perpendicularly to longitudinal axis L_{426} is equal to the cosine of orientation angle A_{430}.

As orientation angle A_{430} approaches 90°, the inclination of endwall 430 becomes negligible. Correspondingly, the size of the fractional portion of the force of any fluid jet

infused through slit 434 that is directed perpendicularly to longitudinal axis L_{426} approaches zero. The size of the fractional portion of the force of any fluid jet infused through slit 434 that is in alignment with longitudinal axis L_{426} approaches unity, a situation illustrated by arrow I in Figure 11B. As orientation angle A_{430} approaches 90°, however, correspondingly decreased is maximum diametrical extent E_{430max} of endwall 430 and the potential length S_{434} of slit 434. Conversely, as the inclination of endwall 430 increases, the size of orientation angle A_{430} decreases, resulting in an increasingly smaller fractional portion of the force of any fluid jet infused from catheter device 424 through slit 434 being aligned with longitudinal axis L_{426}.

Steps in a method for manufacturing an inclined endwall of uniform thickness, such as endwall 430 in which to form a slit to be used as a valve, are similar to those presented in the sequence of Figures 12A-12E. It should be noted, however, that the manufacture of an endwall, such as endwall 430 in which to form a slit to be used as a valve, could also be implemented according to the teachings of the present invention using steps similar to those employing the fusion bonding technique presented in the sequence of Figures 22A-22G.

In addition, an inclined planar endwall of uniform thickness, such as endwall 430, can be manufactured as an endwall attached directly to the distal surface of the outer wall of a catheter tube using the method by which endwall 28 of distal tip 24 of catheter tube 14 is manufactured in the steps presented in the sequence of Figures 5A-5E. Alternatively, an inclined planar endwall of uniform thickness, such as endwall 430, can be manufactured as an endwall attached directly to inner surface 36 of outer wall 26 using the method by which endwall 80 of distal tip 78 of catheter tube 14 is manufactured in the steps presented in the sequence of Figures 9A-9E. In either case, the distal surface of the outer wall of the catheter

tube utilized is first cut at an angle of inclination that is equal to orientation angle A_{430} of endwall 430 relative to longitudinal axis L_{426} of distal portion 426 illustrated in Figures 28-29.

Thus, it is possible according to the teachings of the present invention to forego the resort to any intermediary structure, such as bonding ring 285 of fusion band 276 or outer wall 438 of distal extension 436, in connecting and contiguously supporting a planar inclined endwall of uniform thickness on the otherwise open distal end of a single lumen catheter tube.

Regardless of the method used to manufacture an inclined planar endwall of uniform thickness, such as endwall 430, the actual configuration of such an endwall is not limited according to teachings of the present invention to being exclusively as depicted in Figures 28-29.

Accordingly, depicted in Figure 30 by way of example is an eleventh embodiment of the distal portion of a single lumen catheter device 464 that incorporates teachings of the present invention. Although the distal portion of catheter device 464 is possessed of an external appearance similar in certain respects to that of catheter device 424 in Figure 27, the distal portion of catheter device 464 includes structural features that contrast with those of catheter device 424.

Catheter device 464 can be seen to terminate in a distal portion 466 having a longitudinal axis L_{466}. Distal portion 466 includes the distal end of catheter tube 14 and a hollow distal extension 468 therefor that is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Distal extension 468 has an outer wall 470 with an inner surface 472 that defines a fluid passageway 474 of length F_{474}. Inner surface 36 of outer

wall 26 of catheter tube 14 at distal surface 38 is smoothly continuous with inner surface 472 of outer wall 470 at proximal end 476 thereof.

Although distal extension 468 is illustrated in Figure 30 as being secured directly to and supported by outer wall 26 of catheter tube 14, outer wall 470 of distal extension 468 can, in the alternative, be bonded indirectly to distal surface 38 of outer wall 26 of catheter tube 14 using an intermediary structure, such as bonding ring 285 illustrated in Figures 20-21.

Distal end 478 of outer wall 270 of distal extension 468 is closed by a planar endwall 480 that is continuously supported by outer wall 470 of distal extension 468 at distal end 478 thereof. Endwall 480 has an outer surface 482 and an inner surface 484. The periphery 486 of outer surface 482 of endwall 480 is also located on the exterior of outer wall 470 of distal extension 468, whereby periphery 486 of outer surface 482 of endwall 480 is the intersection of the exterior surface of each.

Although not immediately apparent from the cross section view of Figure 30, periphery 486 of outer surface 482 of endwall 480 is an ellipse having a maximum diametrical extent E_{480max} measured along the major axis of that ellipse. Periphery 486 of outer surface 482 of endwall 480 defines a plane P_{480} of endwall 480 that forms an acute orientation angle A_{480} with longitudinal axis L_{466} of distal portion 466 of catheter device 464. Thus, endwall 480 is inclined relative to longitudinal axis L_{466}. Advantageously, the inclination of endwall 480 permits maximum diametrical extent E_{480max} thereof to be greater than diameter D_{14} of the exterior of catheter tube 14.

In contrast to the inventive embodiment illustrated in Figures 28-29, the area of fluid passageway 474 in a transverse cross section of distal extension 468 at proximal end 476 of

outer wall 470 is less than the area of fluid passageway 474 in a transverse cross section of distal extension 468 adjacent endwall 480 at distal end 478 of outer wall 470. Therefore, fluid passageway 474 includes an enlarged distal terminus 488 at which inner surface 472 of outer wall 470 flares radially outwardly from longitudinal axis L_{466} forming a frustoconical surface 490 that encircles distal terminus 488. The periphery 492 of frustoconical surface 490 takes the form of a small-radius fillet that smoothly connects frustoconical surface 490 with inner surface 484 of endwall 480. At periphery 492 of frustoconical surface 490, the thickness of outer wall 470 is identified in Figure 30 as thickness T_{492}.

The transverse cross section of the exterior of outer wall 470 of distal extension 468 is unchanged along the full length thereof. Therefore, at distal terminus 488 of fluid passageway 474, frustoconical surface 490 produces a corresponding tapered wall structure 494 at distal end 478 of outer wall 470. The thickness of tapered wall structure 494 reaches a minimum at periphery 492 of frustoconical surface 490 that is equal to thickness T_{492}. A slit 496 extends between outer surface 482 and inner surface 484 of endwall 480, as well as through the exterior of distal end 478 of outer wall 470 of distal extension 466.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by an inclined planar terminal endwall of enhanced maximum diametrical extent is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 496 in endwall 480 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by an inclined planar terminal endwall of enhanced maximum diametrical extent is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 496 in endwall 480 is a structure capable of performing the three functions of a selectively operable fluid transport means according to the teachings of the present invention.

Slit 496 intersects longitudinal axis L_{466} of distal portion 466 and is contained in the plane associated with the cross section illustrated in Figure 29. Accordingly, Figure 29 depicts only a first slit face 498 of the two opposed slit faces that are normally engaged in the closed position of slit 496 in which distal terminus 488 of fluid passageway 474 is isolated from the exterior of distal portion 466 of catheter device 464.

Slit face 498 is an elongated, somewhat parallelogrammatic, C-shaped surface bounded by an outer edge 500 and an inner edge 502. Outer edge 500 includes an elongated straight central portion 504, a relatively short straight end portion 506 at a first end thereof, an interconnecting rounded corner fillet 508 therebetween, and a rounded terminal corner fillet 509 at the second end of straight central portion 504. Central portion 504 of outer edge 500 coincides with outer surface 482 of endwall 480, while end portion 506 coincides with the exterior of outer wall 470 at distal end 478 thereof. Corner fillets 508, 509 are located on periphery 486 of outer surface 482 of endwall 480. The distance between terminal corner fillet 509 and the proximal terminus of end portion 506 defines the length S_{496} of slit 496. As shown in Figure 30, length S_{496} of slit 496 is approximately equal to maximum diametrical

extent E_{480max} of endwall 480. Accordingly, length S_{496} of slit 496 is advantageously greater even than diameter D_{14} of the exterior of catheter tube 14.

Inner edge 502 of slit face 498 includes an elongated central portion 510 and a terminal corner fillet 512 at each end thereof. Central portion 510 of inner edge 502 of slit face 498 coincides with inner surface 484 of endwall 480, while terminal corner fillets 512 coincide with the interior of tapered wall structure 494 at periphery 492 of frustoconical surface 490. Central portion 504 of outer edge 500 and central portion 510 of inner edge 502 are separated by a distance equal to thickness T_{480} of endwall 480.

The extreme ends of slit face 498 are located at periphery 492 of frustoconical surface 490. There, the opposed ends of outer edge 500 and inner edge 502 are joined by respective slit face junctions 514, 516. It is at slit face junctions 514, 516, that the opposed ends of the slit faces of slit 496 are permanently secured together. Slit face junctions 514, 516, are shown by way of illustration in Figure 30 as being colinear with each other and parallel to central portion 504 of outer edge 500 of slit face 498. As a result, slit face junctions 514, 516, form angles with the exterior of outer wall 470 of distal extension 468 that are supplementary to each other. Consequently, at slit face junctions 514, 516, outer edge 500 and inner edge 502 are separated by a distance that is somewhat greater than thickness T_{492} of tapered wall structure 494 at periphery 492 of frustoconical surface 490.

Nonetheless, specific desirable functional characteristics in a slit, such as slit 496 intended to be operated as a valve, may dictate that slit face junctions 514, 516, be non-colinear or be oriented individually at unequal angles relative to respective end portions 506, 509, of outer edge 500 of slit face 498. In addition, one or both of slit face junctions 514, 516, can be

positioned proximally along outer wall 470 of distal extension 468 from the position thereof shown in Figure 30.

From Figure 30 it is clear that providing slit 496 in endwall 480, and securing endwall 480 to outer wall 26 of catheter tube 14, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 464 and at no increase in the size of the outer cross section of distal portion 466 of catheter device 464.

The three positions assumable by slit 496 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the operation of slit 496 in endwall 480 when operated as a valve are similar to those described in relation to each of these sets of figures with the minor qualification arising from the inclination of endwall 480 described above relative to inclined endwall 430 of Figures 28-29.

Steps in a method for manufacturing an inclined endwall of uniform thickness and enhanced maximum diametrical extent, such as endwall 480 in which to form a slit to be used as a valve, are similar to those presented in the sequence of Figures 22A-22G, except that the use of the fusion bonding technique presented in that sequence has been omitted in the manufacture of catheter device 464.

Regardless of the method used to manufacture an inclined planar endwall of uniform thickness and extended maximum diametrical extent, such as endwall 480, the actual configuration of such an endwall is not limited according to the teachings of the present invention to being exclusively as depicted in Figure 30.

Accordingly, depicted in Figure 31 by way of example is a twelfth embodiment of the distal portion of a single lumen catheter device 524 that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive embodiments illustrated and disclosed previously. Catheter device 524 is there seen to have a distal portion 526 with a longitudinal axis L_{526} and a closed distal tip 528. Distal tip 528 of catheter device 524 includes a circumferential outer wall and an arcuate terminal endwall 530 continuously supported by that circumferential outer wall. The periphery 532 of endwall 530 is also located on the exterior of that circumferential outer wall, whereby periphery 532 is the intersection of the exterior surface of each.

Periphery 532 of endwall 530 is an ellipse having a maximum diametrical extent E_{530max} measured along the major axis of that ellipse and a minimum diametrical extent E_{530min} measured perpendicular thereto along the minor axis of that ellipse. Periphery 532 of endwall 530 defines a plane P_{530} of endwall 530 that forms an acute orientation angle A_{530} with longitudinal axis L_{526} of distal portion 526 of catheter device 524. Thus, endwall 530 is inclined relative to longitudinal axis L_{526}. Extending diametrically across substantially the full length of the longest dimension of endwall 530 is the visible outer edge of a linear slit 534 that intersects longitudinal axis L_{526} of distal portion 526.

According to an aspect of the present invention, a single lumen catheter tube having a distal end closed by an inclined arcuate terminal endwall is provided with selectively operable stagnation suppression means that performs the function thereof disclosed in detail previously. Slit 534 in endwall 530 in Figure 31 is an example of structure capable of performing the

function of a selectively operable stagnation suppression means according to teachings of the present invention.

According to another aspect of the present invention, a single lumen catheter tube having a distal end closed by an inclined arcuate terminal endwall is provided with selectively operable fluid transport means that performs the three functions thereof disclosed in detail previously. Slit 534 in endwall 530 in Figure 31 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention.

In the cross section view presented in Figure 32, distal portion 526 of catheter device 524 can be seen to include the distal end of catheter tube 14 and a distal extension 536 therefor that is attached to the otherwise open distal end of catheter tube 14 at distal surface 38 of outer wall 26. Distal extension 536 has an outer wall 538 with an inner surface 540 that defines a fluid passageway 542 of length F_{542}. The otherwise open proximal end 544 of outer wall 538 of distal extension 536 is attached to catheter tube 14. Inner surface 36 of outer wall 26 of catheter tube 14 at distal surface 38 is smoothly continuous with inner surface 540 of outer wall 538 at proximal end 544 thereof.

Although distal extension 536 is illustrated in Figure 32 as being secured directly to and supported by outer wall 26 of catheter tube 14, outer wall 538 of distal extension 536 can, in the alternative, be bonded indirectly to distal surface 38 of outer wall 26 of catheter tube 14 using an intermediary structure, such as bonding ring 285 illustrated in Figures 20-21.

As shown by way of illustration, endwall 530 is an arcuate structure that extends across the otherwise open distal end 546 of outer wall 538 of distal extension 536 and is continuously

supported by distal end 546 of outer wall 538. Endwall 530 is secured to outer wall 538 by any of a number of appropriate methods, which have been discussed previously or will be discussed below.

Endwall 530 has a spherical outer surface 548 generated at a radius of curvature R_{548} about a center of curvature C_{530} that is located on the outer surface of outer wall 538 of distal extension 536. Inner surface 550 of endwall 530 is also a spherical surface, but a spherical surface generated at a radius of curvature R_{550} about center of curvature C_{530}. Thus, outer surface 548 is concentric with inner surface 550, and endwall 530 exhibits a radially uniform thickness T_{530} that is equal to the difference between radius of curvature R_{548} of outer surface 548 and radius of curvature R_{550} of inner surface 550.

Radius of curvature R_{550} of inner surface 550 is less than diameter D_{14} of catheter tube 14 by an amount that is less than thickness T_{26} of outer wall 26 of cathêter tube 14. Accordingly, the periphery 552 of inner surface 550 of endwall 530 is at all locations thereon a non-tangential intersection with inner surface 540 of outer wall 538 of distal extension 536. Although not immediately apparent from Figure 32, periphery 552 of inner surface 540 of endwall 530 is an ellipse that is inclined relative to longitudinal axis L_{526} of distal portion 526.

Radius of curvature R_{548} of outer surface 548 of endwall 530 is, however, equal to diameter D_{14} of catheter tube 14. Accordingly, the intersection of outer surface 548 of endwall 530 with the exterior of outer wall 538 of distal extension 536 is a continuously smooth merger of surfaces only on the side of distal extension 536 opposite from center of curvature C_{530} in the vicinity of the proximal extremity of slit 534 in the plane identified by section line 32-32 in Figure 31. The balance of periphery 532 of endwall 530 is a non-tangential

intersection of outer surface 548 of endwall 530 with the exterior of outer wall 538 of distal extension 536.

Regardless of the method used to manufacture catheter device 524, the material properties of endwall 530 need not be identical to those of outer wall 26 of catheter tube 14. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 32 it is clear that providing slit 534 in endwall 530, and securing endwall 530 to outer wall 26 of catheter tube 14, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumen within catheter device 524, and at no increase in the size of the outer cross section of distal portion 526 of catheter device 524.

Figure 32 depicts only a first slit face 554 of the two opposed slit faces that are normally engaged in the closed position of slit 534 in which fluid passageway 542 is isolated from the exterior of distal extension 536.

Slit face 554 has an elongated, curved configuration, being bounded along the longer, curved dimension thereof by an acute outer edge 556 and an acute inner edge 558 that is concentric with outer edge 556. Outer edge 556 of slit face 554 coincides with outer surface 548 of endwall 530, while inner edge 558 of slit face 554 coincides with inner surface 550 of endwall 530. Thus, outer edge 556 and inner edge 558 are separated radially by a uniform distance equal to thickness T_{530} of endwall 530.

At the extremes of slit face 554, the opposed ends of outer edge 556 and inner edge 558 are joined respectively by slit face junctions 560, 562. It is at slit face junctions 560, 562, that the opposite ends of the slit faces of slit 534 are permanently secured together.

The distance between slit face junctions 560, 562, measured concentrically with center of curvature C_{530} defines the length S_{534} of slit 534. As a result of the inclination and of the curvature of endwall 530, length S_{534} of slit 534 is larger even than diameter D_{14} of the exterior of catheter tube 14. Slit face junctions 560, 562, as shown in Figure 31, are not parallel to each other. Only slit face junction 562 is parallel to longitudinal axis L_{526} of distal portion 526. Nonetheless, specific desirable functional characteristics of a slit, such as slit 534 to be operated as a valve, may dictate other orientations for slit face junctions 560, 562.

The three positions assumable by slit 534 when operated as a valve are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantage of the operation of slit 534 in endwall 530 when operated as a valve are similar to those described in relation to each of these sets of figures, with the qualification resulting from the inclination of endwall 530, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28-29.

Steps in a method for manufacturing an inclined arcuate endwall of uniform thickness and enhanced maximum diametrical extent, such as endwall 530 in which to form a slit to be used as a valve, are similar to those presented in the sequence of Figures 12A-12E. It should be noted, however, that the manufacture of an endwall, such as endwall 530, could be implemented according to teachings of the present invention using the fusion bonding techniques presented in the sequence of Figures 22A-22G.

Regardless of the method used to manufacture an inclined arcuate endwall of uniform thickness and extended maximum diametrical extent, such as endwall 530, the actual

configuration of such an endwall is not limited according to the teachings of the present invention to being exclusively as depicted in Figures 31-32.

Thus, Figure 33 depicts patient 250 for whom a therapeutic procedure is once again to be undertaken on an intermittent basis in superior vena cava 12 of the venous subsystem of the cardiovascular system. The required access to superior vena cava 12 is provided through the implantation of a catheter device 564 that includes a catheter tube 566 and a distal portion 568 with a closed distal tip 570 that is intended to reside in superior vena cava 12 and that incorporates teachings of the present invention.

As illustrated in the transverse cross section view presented in Figure 34, catheter tube 566 is a dual lumen catheter tube that includes a cylindrical circumferential outer wall 572 with an inner surface 574 and a planar septum 576 that extends between distinct nonadjacent locations on inner surface 574. Consequently, the interior of catheter tube 566 is separated by septum 576 into a pair of longitudinally extending fluid flow lumens 578, 580. Lumen 578 is defined by a first side 582 of septum 576 and a first portion 584 of inner surface 574 of outer wall 572 adjacent to first side 582 of septum 576. Lumen 580 is located on the opposite side of septum 576 from lumen 578, whereby lumen 580 is defined by a second side 586 of septum 576 and a second portion 588 of inner surface 574 of outer wall 572 adjacent to second side 586 of septum 576. As illustrated in Figure 34, the thickness T_{576} of septum 576 can be less than the thickness T_{572} of outer wall 572 of catheter tube 566. Septum 576 is diametrically disposed within the transverse cross section of catheter tube 566, whereby lumens 578, 580, present identical D-shaped configurations in that cross section.

As shown in Figure 33, the proximal end 590 of catheter tube 566 exits vein 260 of the venous subsystem of the cardiovascular system in upper arm 592 of patient 250. Proximal end 590 of catheter tube 566 is attached to a vascular access port 594 that encloses a pair of fluid reservoirs, each accessible on a selective basis through a respective needle-penetrable septum 596. Access port 594 with proximal end 590 of catheter tube 566 attached thereto is embedded subcutaneously in the tissue of upper arm 592, but outside of the cardiovascular system. To conduct a therapeutic procedure using catheter device 564, a respective one of the fluid reservoirs in access port 594 is accessed with the tip of needle 266 of hyperdermic syringe 268. The tip of needle 266 is first advanced through the tissue of upper arm 592 overlying access port 594 and then through a corresponding one of needle-penetrable septums 596. Catheter device 564 in combination with access port 594 thus functions as a venous access system 598. When catheter device 564 is not in active use, syringe 268 is withdrawn, and no portion of venous access system 598 is exposed external of the body of patient 250.

Figure 35 is an enlarged perspective view of distal portion 568 of catheter device 564 shown in Figure 33. Distal portion 568 of catheter device 564 is there seen to have a longitudinal axis L_{568}, and distal tip 570 of catheter device 564 includes a planar terminal endwall 600 continuously supported by outer wall 572 of catheter tube 566. The periphery 602 of endwall 600 is also located on outer wall 572 of catheter tube 566, whereby periphery 602 is the intersection of the outer surface of each. Periphery 602 of endwall 600 is a circle that defines a plane P_{600} of endwall 600. Plane P_{600} is perpendicular to longitudinal axis L_{568} of distal

portion 568 of catheter device 564. Extending diametrically across endwall 600 is a colinear pair of distinct slits 604, 606, of equal length.

According to an aspect of the present invention, a catheter tube having a plurality of longitudinally extending fluid flow lumens and a closed distal end closed by a terminal endwall is provided with selectively operable stagnation suppression means associated with one or both of those lumens that performs the function of effecting fluid flow through a respective region of each of the lumens of the catheter tube immediately adjacent the terminal endwall, doing so only in response to predetermined positive and negative pressure differentials between a respective lumen and the exterior of the catheter tube. Each of slit 604, 606, in endwall 600 shown in Figure 35 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 564.

According to another aspect of the present invention, a catheter tube having a plurality of longitudinally extending fluid flow lumens and a distal end closed by a terminal endwall is provided with selectively operable fluid transport means associated with one or both of those lumens that performs three functions relative to such an associated lumen. First, a fluid transport means according to teachings of the present invention functions to close the distal end of the associated lumen of the catheter on a selective basis. Second, the fluid flow transport means functions to infuse a fluid from the associated lumen of the catheter in a direction generally aligned with the longitudinal axis of the distal portion of the catheter, when a predetermined positive pressure differential exists between the associated lumen and the exterior of the distal portion of the catheter. Finally, the fluid transport means functions to aspirate fluid

from the exterior of the catheter into the associated lumen thereof, when a predetermined negative pressure differential exists between the associated lumen and the exterior of the distal portion of the catheter. Each of slits 604, 606, in endwall 600 shown in Figure 35 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to the teachings of the present invention for an associated lumen of catheter device 564.

The elevation cross section view of distal portion 568 of catheter tube 566 presented in Figure 36, depicts the pair of longitudinally extending fluid flow lumens 578, 580, defined previously in relation to Figure 34. Endwall 600 extends across the otherwise open distal end of lumens 578, 580, and is continuously supported by combination of the annular distal surface 608 of outer wall 572 and the substantially rectangular distal surface 610 of septum 576. Endwall 600 is secured to distal surface 608 of outer wall 572 and to distal surface 610 of septum 576 by any of the appropriate methods disclosed previously. Endwall 600 has an outer surface 612 visible but not labeled in Figure 35 and an inner surface 614 that is parallel thereto. Accordingly, endwall 600 has a thickness T_{600} that is equal to the distance between outer surface 612 and inner surface 614 thereof.

Slit 604 is formed through endwall 600 at a location that permits slit 604 to be associated with lumen 578 when slit 604 is operated as a valve. Similarly, slit 606 is formed through end wall 600 at a location that permits slit 606 to be associated with lumen 580 when slit 606 is operated as a valve. As slits 604, 606, are substantially similar in structural detail, only features of slit 604 will be described further herein.

Figure 36 depicts only a first slit face 616 of the two opposed slit faces that are normally engaged in the closed position of slit 604 in which lumen 578 is isolated from the exterior of distal portion 568 of catheter tube 566. Slit face 616 is substantially rectangular in configuration, being bounded along the longer extent thereof by an outer edge 618 and an inner edge 620 that is parallel thereto. Outer edge 618 and inner edge 620 are separated by a distance equal to thickness T_{600} of endwall 600. Outer edge 618 coincides with outer surface 612 of endwall 600 and is thus the only portion of slit face 616 that is in theory visible in Figure 35. Inner edge 620 of slit face 616 coincides with inner surface 614 of endwall 600.

At the extremes of slit face 616, the opposed ends of outer edge 618 and inner edge 620 are joined by respective slit face junctions 622, 624, where the opposite ends of the slit faces of slit 604 are permanently secured together. The distance between slit face junctions 622, 624, defines the length S_{604} of slit 604. The corresponding length S_{606} of slit 606 is shown in Figure 36 as being less than half of diameter D_{574} of inner surface 574 of outer wall 572 of catheter tube 566.

Slit face junctions 622, 624, are shown in Figure 36 by way of illustration as being both parallel to each other and perpendicular to outer edge 618 of slit face 616. Nonetheless, slit face junctions 622, 624, are less likely than outer edge 618 and inner edge 620 to be truly parallel to each other. Specific desirable functional characteristics of a slit, such as slit 604 operated as a valve, may dictate that slit face junctions 622, 624, be nonparallel, or be oriented individually at equal or unequal acute or obtuse angles, respectively, relative to outer edge 618 of slit face 616.

An orthogonally oriented view in cross section of the structures illustrated in Figure 36 is presented in Figure 37. There, slit 604 appears on edge.

From Figures 36-37 taken together, it is clear that providing slits 604, 606, in endwall 600, and securing endwall 600 to outer wall 572 of catheter tube 566, are accomplished at no loss in the size of the cross section of longitudinally extending fluid flow lumens within catheter device 564, and at no increase in the size of the outer cross section of distal portion 568 of catheter device 564.

The three positions assumable individually by slits 604, 606, are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the individual operation of slits 604, 606, as valves are similar to those described in relation to each of these sets of figures.

Steps in a method for manufacturing an endwall for a dual lumen catheter device, such as endwall 600 in which to form one or more slits to be used as valves, are similar to those presented in the sequence of Figures 9A-9E, except that dual lumen catheter tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. Regardless of the method used to manufacture catheter device 564, the material properties of end wall 600 need not be identical to those of outer wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figures 36-37, it is clear that providing slits 604, 606, in endwall 600, and securing endwall 600 to outer wall 572 and to septum 576 of catheter tube 566, are

accomplished at no loss in the size of the cross section of the pair of longitudinally extending fluid flow lumens within catheter device 564, and at no increase in the size of the outer cross section of distal portion 568 of catheter device 564.

The positioning and configuration of one or more slits formed according to teachings of the present invention in the endwall of a dual lumen catheter device need not be exclusively as depicted in Figures 35-37. Linear slits, such as slits 604, 606, are relatively easy to form and are possessed of relatively predictable behavior.

The positioning of a slit, such as slit 604, in a diametrical relationship to the endwall through which the slit is formed and in a perpendicular relationship to a septum that defines a portion of the lumen with which the slit is associated, produces a slit of intermediate length relative to the dimensions of the endwall. Specific medical applications can require that alternative arrangements be adopted.

Accordingly, slit 604 could, for example, be positioned within endwall 600 radially offset from longitudinal axis L_{568} of distal portion 568 in a manner similar to the radially offset positioning in endwall 80 of slit 84 illustrated in Figures 6-8. A slit offset in this manner from the position illustrated in Figure 35 would, if oriented perpendicular to septum 576, have a length less than length S_{604} of slit 604.

It has often been found desirable, however, to maximize the length of a slit, such as slit 604 in the endwall of a dual lumen catheter. Accordingly, in Figure 38 is an enlarged view of distal portion 568 of catheter device 564 with various possible alternative orientations of and positions for such a slit associated with lumen 578 therein. Slit 606, which is associated with

lumen 580 when operated as a valve, is shown in the same position and orientation thereof as in Figures 35-36.

Length S_{604} of slit 604 associated with lumen 578 can be increased by altering the orientation or the position of the slit within the portion of endwall 600 that affords access to lumen 578. Thus, for example, slit 604-1 is greater in length than slit 604, because slit 604-1 is oriented at an acute, rather than at a right, angle to septum 576. Slit 604-2 is greater in length than slit 604-1, because slit 604-2 is further inclined away from being perpendicular to septum 576 than is slit 604-1. Also, slit 604-2 has been positioned on endwall 600 closer to septum 576 than slit 604-1, which contributes to increased length in slit 604-2.

Slit 604-3 is parallel to septum 576. Due to the position of slit 604-3 relative to endwall 600, slit 604-3 is greater in length than slit 604-2. Slit 604-4 is also parallel to septum 576, but slit 604-4 has a greater length than slit 604-3, because slit 604-4 is positioned on endwall 600 in closer proximity to septum 576 than is slit 604-3.

Finally, slit 604-5, which is also parallel to septum 576, has a greater length than even slit 604-4, because slit 604-5 traverses the full width of endwall 600 in close proximity to septum 576. Accordingly, the visible outer edge of slit 604-5 assumes a 90-degree bend at circular periphery 602 of endwall 600.

Each of slit 604-1, slit 604-2, slit 604-3, slit 604-4, and slit 604-5 is an example of structure capable of performing the three functions of a selectively operable fluid transport means relative to lumen 578 according to teachings of the present invention.

Nonetheless, it is possible according to teachings of the present invention to afford for yet further length in a slit that is to be used as a valve in the distal endwall of a dual lumen

catheter. Accordingly, depicted in Figure 39 by way of example is a second embodiment of the distal portion of dual lumen catheter device 634 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to the inventive embodiments illustrated and discussed previously. Catheter device 634 is there seen to have a distal portion 636 with a longitudinal axis L_{636} and a closed distal tip 638.

Distal tip 638 of catheter device 634 includes a circumferential outer wall and a planar terminal endwall 640 continuously supported by that circumferential outer wall. The periphery 642 of endwall 640 is also located on that circumferential outer wall, whereby periphery 642 is the intersection of the outer surface of each. Periphery 642 of endwall 640 is a circle that defines a plane P_{640} of endwall 640. Plane P_{640} is perpendicular to longitudinal axis L_{636} of distal portion 636 of catheter device 634. Extending diametrically across the full extent of endwall 640 is a parallel pair of distinct slits 644, 646, of equal length. The visible outer edge of each of slits 644, 646, assumes a 90-degree bend at periphery 642 of endwall 640.

According to an aspect of the present invention, a catheter tube having a plurality of longitudinally extending fluid flow lumens and a distal end closed by a terminal endwall is provided with selectively operable stagnation suppression means associated with one or both of those lumens for performing the function disclosed in detail previously. Each of slits 644, 646, in endwall 640 shown in Figure 39 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 634.

According to another aspect of the present invention, a catheter tube having a plurality of longitudinally extending fluid flow lumens and a distal end closed by a terminal endwall is

provided with selectively operable fluid transport means associated with one or both of those lumens that performs the three functions thereof disclosed in detail previously. Each of slits 644, 646, in endwall 640 shown in Figure 39 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to the teachings of the present invention for an associated lumen of catheter device 634.

In the cross section view presented in Figure 40, distal portion 636 of catheter device 634 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 648 therefor. Distal extension 648 has an outer wall 650 with an inner surface 652 and a planar interior wall 654 that extends between distinct nonadjacent locations on inner surface 652. Consequently, the interior of distal extension 648 is separated by interior wall 654 into a first fluid passageway 656 of length L_{656} and a second fluid passageway 658 of length L_{658}. First fluid passageway 656 is defined by a first side 660 of interior wall 654 and a first portion 662 of inner surface 652 of outer wall 650 that is adjacent to first side 660 of interior wall 654. Second fluid passageway 658 is located on the opposite side of interior wall 654 from first fluid passageway 656, whereby second fluid passageway 658 is defined by a second side 664 of interior wall 654 and a second portion 666 of inner surface 652 of outer wall 650 that is adjacent to second side 664 of interior wall 654. As illustrated in Figure 40, the thickness of interior wall 654 is equal to thickness T_{576} of septum 576 of catheter tube 566.

First portion 584 of inner surface 574 of outer wall 572 of catheter tube 566 at distal surface 608 is smoothly continuous with first portion 662 of inner surface 652 of outer wall 650 of distal extension 648. First side 582 of septum 576 of catheter tube 566 at distal surface 610

is smoothly continuous with first side 660 of interior wall 654 of distal extension 648. Lumen 578 of catheter tube 566 is, therefore, identical in transverse cross section with the transverse cross section of fluid passageway 656 of distal extension 648 at proximal end 672 of outer wall 650 thereof.

Second portion 588 of inner surface 574 of catheter tube 566 at distal surface 608 is smoothly continuous with second portion 666 of inner surface 652 of outer wall 650 of distal extension 648. Second surface 586 of septum 576 of catheter tube 566 at distal surface 610 is smoothly continuous with second side 664 of interior wall 654 of distal extension 648. Thus, lumen 580 of catheter tube 566 is identical in transverse cross section with the transverse cross section of second fluid passageway 658 of distal extension 648 at proximal end 672 of outer wall 650 thereof.

Endwall 640 extends across the otherwise open distal ends of first fluid passageway 656 and second fluid passageway 658 and is continuously supported by the combination of outer wall 650 and interior wall 654 of distal extension 648. Endwall 640 is secured to outer wall 650 and interior wall 654 of distal extension 648 by any of the appropriate methods disclosed previously. Endwall 640 has an outer surface 668 visible but not labeled in Figure 39, and an inner surface 670 that is parallel thereto. Accordingly, endwall 640 has a thickness T_{640} that is equal to the distance between outer surface 668 and inner surface 670 thereof.

In Figure 40, slits 644, 646, each appear on edge only. Slits 644, 646, are located within endwall 640 in proximity to interior wall 654, but on opposite sides thereof. Slit 644 extends between outer surface 668 and inner surface 670 of endwall 640 at a position on

endwall 640 that affords access to fluid passageway 656. Slit 646 extends between outer surface 668 and inner surface 670 of endwall 640 at a position on endwall 640 that affords access to fluid passageway 658.

In contrast to the inventive embodiment disclosed in Figures 35-37, the area of first fluid passageway 656 in a transverse cross section of distal extension 648 at proximal end 672 of outer wall 650 is less than the area of fluid passageway 656 in a transverse cross section of distal extension 648 at distal end 674 of outer wall 650 adjacent to endwall 640. Therefore, first fluid passageway 656 includes an enlarged distal terminus 676 at which first portion 662 of inner surface 652 of outer wall 650 flares radially outwardly from longitudinal axis L_{636} to form a first frustoconical surface 678. In combination with the distal portion of first side 660 of interior wall 654, first frustoconical surface 678 encircles distal terminus 676 of first fluid passageway 656. The periphery 680 of first frustoconical surface 678 takes the form of a small-radius fillet that smoothly connects first frustoconical surface 678 with inner surface 670 of endwall 640. At periphery 680 of first frustoconical surface 678, the thickness of outer wall 650 is identified in Figure 40 as a thickness T_{680}.

Second fluid passageway 658 is similarly configured. Thus, second fluid passageway 658 includes an enlarged distal terminus 682 at which second portion 666 of inner surface 652 of outer wall 650 flares radially outwardly from longitudinal axis L_{636} of distal portion 636 to form a second frustoconical surface 684. In combination with the distal portion of second side 664 of interior wall 654, second frustoconical surface 684 encircles distal terminus 682 of second fluid passageway 658. The periphery 686 of second frustoconical surface 684 takes the form of a small-radius fillet that smoothly connects second frustoconical

surface 684 with inner surface 670 of endwall 640. At periphery 686 of second frustoconical surface 684, the thickness of outer wall 650 is identified in Figure 40 as a thickness T_{686}.

The transverse cross section of the exterior of outer wall 650 of distal extension 648 is unchanged along the full length thereof. Therefore, at distal terminus 676 of first fluid passageway 656, first frustoconical surface 678 produces a corresponding first tapered wall structure 681 at distal end 674 of outer wall 650. The thickness of first tapered wall structure 681 and of outer wall 650 reaches a minimum at periphery 680 of first frustoconical surface 678 that is equal to thickness T_{680}. Distal of periphery 680 of first frustoconical surface 678, outer wall 650 of distal extension 648 increases in thickness.

For similar reasons, second frustoconical surface 684 produces a corresponding second tapered wall structure 687 at distal end 674 of outer wall 650.

The reduction in the thickness of outer wall 650 at first tapered wall structure 681 and at second tapered wall structure 687 correspondingly and advantageously permits an enhancement of the diametrical extent E_{640} of endwall 640. The increase thusly afforded in diametrical extent E_{640} of endwall 640 is directly related to the amounts of the thinning of outer wall 650 at periphery 680 of first frustoconical surface 678 and at periphery 686 of second frustoconical surface 684. Accordingly, as illustrated in Figure 41, diametrical extent E_{640} of endwall 640 is larger than diameter D_{574} of inner surface 574 of outer wall 572 of catheter tube 566.

As slits 644, 646, are substantially similar in structural detail, only features of slit 644 will be described further herein. Slit 644 is contained in the plane identified by section line 41-41 in Figures 39 and 40. Accordingly, Figure 41 depicts only a first slit face 688 from

among the pair of opposed slit faces that are normally engaged in the closed position of slit 644 in which first fluid passageway 656 is isolated from the exterior of distal portion 636 of catheter device 634.

Slit face 688 is an elongated, substantially rectangular surface bounded along the longer extent thereof by an outer edge 690 and an inner edge 692 that is parallel thereto. Outer edge 690 includes an elongated straight central portion 694 and a pair of short end portions 696 disposed perpendicular thereto and interconnected therewith by individual round corner fillets 698. Central portion 694 of outer edge 690 coincides with outer surface 668 of endwall 640, while end portions 696 coincide with the exterior of outer wall 650 at distal end 674 thereof. Corner fillets 698 are thus located on periphery 642 of endwall 640. The distance between end portions 696 of outer edge 690 defines the length S_{644} of slit 644. As shown in Figure 41, length S_{644} is larger than diameter D_{574} of inner surface 574 of outer wall 572 of catheter tube 566. Inner edge 692 of slit face 688 coincides with inner surface 670 of endwall 640. Inner edge 692 of slit face 688 and central portion 694 of outer edge 690 are separated by a distance equal to thickness T_{640} of endwall 640.

At the extreme ends of slit face 688, the opposed ends of outer edge 690 and inner edge 692 are joined by respective slit face junctions 700, 702. It is at slit face junctions 700, 702, that the opposed ends of the slit faces of slit 644 are permanently secured together. At slit face junctions 700, 702, outer edge 690 and inner edge 692 are separated by a distance that is slightly larger than thickness T_{680}.

Slit face junctions 700, 702, are shown in Figure 41 by way of illustration as being colinear with each other and with inner edge 692 of slit face 688. Nonetheless, specific

desirable functional characteristics of a slit, such as slit 644 operated as a valve, may dictate that slit face junctions 700, 702, be nonparallel, be oriented individually at equal or unequal acute or obtuse angles, respectively, relative to end portion 696 of outer edge 690 of slit face 688, or be located proximally along outer wall 650 of distal extension 648 from the position thereof illustrated in Figure 41.

The three positions assumable by slits 644, 646, are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the operation of slits 644, 646, individually or together as valves are similar to those described in relation to each of these sets of figures.

Steps in a method for manufacturing an endwall for a dual lumen catheter device, such as endwall 640 in which to form one or more slits to be used as valves, are similar to those presented in the sequence of Figures 22A-22G, except that dual lumen catheter tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. The fusion bonding technique presented among those figures has not been utilized to manufacture catheter device 634, but that technique does present an acceptable alternative approach to indirectly securing distal extension 648 to distal surface 608 of outer wall 572 and to distal surface 610 of septum 576.

Regardless of the method used to manufacture a planar endwall, such as endwall 640, the actual configuration of such an endwall is not limited according to the teachings of the present invention to being exclusively as depicted in Figures 40-41.

Accordingly, depicted in Figure 42 by way of example is a third embodiment of the distal portion of a dual lumen catheter device 704 that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive embodiments illustrated and disclosed previously. Catheter device 704 is there seen to have a distal portion 706 with a longitudinal axis L_{706} and a closed distal tip 708. Distal tip 708 of catheter device 704 includes a circumferential outer wall and a planar terminal endwall 710 continuously supported by that circumferential outer wall.

The periphery 712 of endwall 710 is also located on the exterior of that circumferential outer wall, whereby periphery 712 is the intersection of the exterior surface of each. Periphery 712 of endwall 710 is an ellipse having a maximum diametrical extent E_{710max} measured along the major axis of that ellipse and a minimum diametrical extent E_{710min} measured perpendicular thereto along the minor axis of that ellipse. Periphery 712 of endwall 710 defines a plane P_{710} of endwall 710 that forms an acute orientation angle A_{710} with longitudinal axis L_{706} of distal portion 706 of catheter device 704. Thus, endwall 710 is inclined relative to longitudinal axis L_{706}. Extending diametrically across endwall 710 on the major axis of periphery 712 is a colinear pair of distinct slits 714, 716, of equal length.

According to an aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by an inclined planar endwall is provided with selectively operable stagnation suppression means associated with one or both of those lumens for performing the function thereof disclosed previously. Each of slits 714, 716, in endwall 710 shown in Figure 42 is an example of structure capable of performing the

function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 704.

According to another aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by an inclined planar endwall is provided with selectively operable fluid transport means associated with one or both of those lumens that performs the three functions thereof discussed previously. Each of slits 714, 716, in endwall 710 shown in Figure 42 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen of catheter device 704.

In the plan cross section view presented in Figure 43, distal portion 706 of catheter device 704 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 718 therefor. Septum 576 of catheter tube 566 is disposed in alignment with the minor diametrical axis of periphery 712 of endwall 710.

Distal extension 718 has an outer wall 720 with an inner surface 722 and a planar interior wall 724 that extends between distinct nonadjacent locations on inner surface 722. Consequently, the interior of distal extension 718 is separated by interior wall 724 into a first fluid passageway 726 of length F_{726} and a second fluid passageway 728 of length F_{728}. Fluid passageway 726 is defined by a first side 730 of interior wall 724 and a first portion 732 of inner surface 722 of outer wall 720 that is adjacent to first side 730 of interior wall 724. Second fluid passageway 728 is located on the opposite side of interior wall 724 from first fluid passageway 726, whereby second fluid passageway 728 is defined by a second side 734 of

interior wall 724 and a second portion 736 of inner surface 722 of outer wall 720 that is adjacent to second side 734 of interior wall 724. As illustrated in Figure 43, the thickness of interior wall 724 is equal to thickness T_{576} of septum 576 of catheter tube 566.

First portion 584 of inner surface 574 of outer wall 572 of catheter tube 566 at distal surface 608 is smoothly continuous with first portion 732 of inner surface 722 of outer wall 720 of distal extension 718. First side 582 of septum 576 of catheter tube 566 at distal surface 610 is smoothly continuous with first side 730 of interior wall 724 at proximal end 742 of outer wall 720 of distal extension 718. Thus, lumen 578 of catheter tube 566 is identical in transverse cross section with the transverse cross section of first fluid passageway 726 of distal extension 718 at proximal end 742 of endwall 720.

Second portion 588 of inner surface 574 of outer wall 572 of catheter tube 566 at distal surface 608 is smoothly continuous with second portion 736 of inner surface 722 of outer wall 720 at proximal end 742 of outer wall 720 of distal extension 718. Second side 586 of septum 576 of catheter tube 566 at distal surface 610 is smoothly continuous with second side 734 of interior wall 724 at proximal end 742 of outer wall 720 of distal extension 718. Thus, lumen 580 of catheter tube 566 is identical in transverse cross section with the transverse cross section of second fluid passageway 728 of distal extension 718 at proximal end 742 of outer wall 720.

End wall 710 extends across the otherwise open distal ends of first fluid passageway 726 and second fluid passageway 728 and is continuously supported by the combination of outer wall 720 and interior wall 724 of distal extension 718. Endwall 710 is

secured to outer wall 720 and interior wall 724 of distal extension 718 by any of the appropriate methods discussed previously.

As understood best by reference to the plan cross section presented in Figure 43, endwall 710 has an outer surface 738 visible but not labeled in Figure 42, and an inner surface 740 that is parallel thereto. Accordingly, endwall 710 has a thickness T_{710} that is equal to the distance between outer surface 738 and inner surface 740 thereof.

Each of slits 714, 716, is contained in the plane identified by section line 43-43 in Figure 42. Slits 714, 716 are formed through endwall 710 on opposite sides of interior wall 724. Slit 714 is formed through endwall 710 at a location that permits slit 714 to be associated with first fluid passageway 726 when slit 714 is operated as a valve. Slit 716 is formed through endwall 710 at a location that permits slit 716 to be associated with second fluid passageway 728 when slit 716 is operated as a valve. As slits 714, 716 are substantially similar in structural detail, only features of slit 714 will be described further herein.

Figure 43 depicts a first slit face 746 of the two opposed slit faces that are normally engaged in the closed position of slit 714 in which first fluid passageway 726 is isolated from the exterior of distal portion 706 of catheter device 704. Slit face 746 is an elongated, rectangular surface bounded along the longer extent thereof by an outer edge 748 and an inner edge 750 that is parallel thereto. At the extreme ends of slit face 746, the opposed ends of outer edge 748 and inner edge 750 are joined by respective slit face junctions 751, 752, at which the opposed ends of the slit faces of slit 714 are permanently secured together. At slit face junctions 751, 752, outer edge 748 and inner edge 750 are separated by a distance equal to thickness T_{710} of endwall 710.

Slit face junctions 751, 752, are shown in Figure 43 by way of illustration as being parallel with each other and perpendicular to outer edge 748 of slit face 746. Nonetheless, specific desirable functional characteristics of a slit, such as slit 714 operated as a valve, may dictate that slit face junctions 751, 752, be nonparallel, or be oriented individually at equal or unequal acute or obtuse angles, respectively, relative to outer edge 748 of slit face 746.

The three positions assumable by slits 714, 716, when operated individual or together as valves are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the operation of slits 714, 716 in endwall 710 when operated individually or together as valves are similar to those described in relation to each of these sets of figures, with the qualification resulting from the inclination of endwall 710, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28 and 29.

Steps in a method for manufacturing an inclined planar endwall of uniform thickness and enhanced maximum diametrical extent, such as endwall 710 in which to form a slit or slits to be used as a valve or valves, are similar to those presented in the sequence of Figures 12A-12E. It should be noted that the manufacture of an endwall, such as endwall 710, could be implemented according to teachings of the present invention using the fusion bonding techniques presented among the sequence of Figures 22A-22G.

Alternatively, an inclined endwall of uniform thickness and enhanced maximum diametrical extent, such as endwall 710, can be attached directly to outer wall 572 and septum 576 of catheter tube 566 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E. Thus, it is possible according to teachings

of the present invention to forego resort to any intermediary structure, such as outer wall 720 and interior wall 724 of distal extension 718, in connecting and continuously supporting an inclined planar endwall of enhanced maximum diametrical extent on the otherwise open distal end of a dual lumen catheter tube.

Regardless of the method used to manufacture catheter device 704, the material properties of endwall 710 need not be identical to those of outer wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 43, it is clear that providing slits 714, 716 in endwall 710, and securing endwall 710 to outer wall 572 and to septum 576 of catheter tube 566, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 704 and at no increase in the size of the outer cross section of distal portion 706 of catheter device 704.

Regardless of the method used to manufacture an inclined planar endwall of extended maximum diametrical extent, such as endwall 710, the actual configuration of such an endwall is not limited according to teachings of the present invention to being exclusively as depicted in Figures 42-44.

Accordingly, depicted in Figure 44 by way of example is a fourth embodiment of the distal portion of a dual lumen catheter device 754 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to the inventive embodiments illustrated and discussed previously. Catheter device 754 is there seen to have a distal portion 756 with a longitudinal axis L_{756} and a closed distal tip 758. Distal tip 758

includes a circumferential outer wall and a planar terminal endwall 760 continuously supported by that circumferential outer wall. The periphery 762 of endwall 760 is also located on that circumferential outer wall, whereby periphery 762 is the intersection of the outer surface of each.

Periphery 762 of endwall 760 is an ellipse having a maximum diametrical extent E_{760max} measured along the major axis of that ellipse and a minimum diametrical extent E_{760min} measured perpendicular thereto along the minor axis of that ellipse. Periphery 762 of endwall 760 defines a plane P_{760} that forms an acute orientation angle A_{760} with longitudinal axis L_{756} of distal portion 756 of catheter device 754. Thus, endwall 760 is inclined relative to longitudinal axis L_{756}. Extending diametrically across substantially the full extent of endwall 760 is a pair of distinct, parallel slits 764, 766, of equal length.

According to an aspect of the present invention, a catheter tube having a plurality of longitudinally extending fluid flow lumens and a distal end closed by an inclined planar endwall is provided with selectively operable stagnation suppression means associated with one or all of those lumens that performs the function thereof disclosed in detail previously. Each of slits 764, 766, in endwall 760 shown in Figure 44 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 754.

According to another aspect of the present invention, a catheter tube having a plurality of longitudinally extending fluid flow lumens and a distal end closed by an inclined planar endwall is provided with selectively operable fluid transport means associated with one or all of those lumens that performs the three functions thereof disclosed in detail previously. Each

of slits 764, 766, in endwall 760 shown in Figure 44 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to the teachings of the present invention for an associated lumen of catheter device 754.

In the elevation cross section view presented in Figure 45, distal portion 756 of catheter device 754 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 768 therefor. In contrast to the orientation of septum 576 of catheter tube 566 in catheter device 704 shown in Figures 42-43, septum 576 of catheter tube 566 in catheter device 754 coincides with the major diametrical axis of periphery 762 of endwall 760.

Distal extension 768 has an outer wall 770 with an inner surface 772 and a planar interior wall 774 that extends between distinct nonadjacent locations on inner surface 772. Consequently, the interior of distal extension 768 is separated by interior wall 774 into a first fluid passageway 776 of length F_{776} and a second fluid passageway 778 of length F_{778}. First fluid passageway 776 is defined by a first side 780 of interior wall 774 and a first portion 782 of inner surface 772 of outer wall 770 that is adjacent to first side 780 of interior wall 774. Second fluid passageway 778 is located on the opposite side of interior wall 774 from first fluid passageway 776, whereby second fluid passage 778 is defined by a second side 784 of interior wall 774 and a second portion 786 of inner surface 772 of outer wall 770 that is adjacent to second side 784 of interior wall 774. As illustrated in Figure 46, the thickness of interior wall 774 is equal to thickness T_{576} of septum 576 of catheter tube 566.

First portion 584 of inner surface 574 of outer wall 572 of catheter tube 566 at distal surface 608 is smoothly continuous with first portion 782 of inner surface 772 at proximal

end 792 of outer wall 770 of distal extension 768. First side 582 of septum 576 of catheter tube 566 at distal surface 610 is smoothly continuous with first side 780 of interior wall 774 at proximal end 792 of outer wall 770 of distal extension 768. Thus, lumen 578 of catheter tube 566 is identical in transverse cross section with the transverse cross section of first fluid passageway 776 of distal extension 768 at proximal end 792 of outer wall 770.

Second portion 588 of inner surface 574 of outer wall 572 of catheter tube 566 at distal surface 608 is smoothly continuous with second portion 786 of inner surface 772 at proximal end 792 of outer wall 770 of distal extension 768. Second side 586 of septum 576 of catheter tube 566 at distal surface 610 is smoothly continuous with second side 784 of interior wall 774 at proximal end 792 of outer wall 770 of distal extension 768. Thus, lumen 580 of catheter tube 566 is identical in transverse cross section with the transverse cross section of second fluid passageway 778 of distal extension 768 at proximal end 792 of outer wall 770.

Endwall 760 extends across the otherwise open distal ends of first fluid passageway 776 and second fluid passageway 778 and is continuously supported by the combination of outer wall 770 and interior wall 774 of distal extension 768. Endwall 760 is secured to outer wall 770 and interior wall 774 of distal extension 768 by any of the appropriate methods disclosed previously.

Appreciated only in Figure 46, endwall 760 has an outer surface 788, visible but not labeled in Figure 44, and an inner surface 790 that is parallel thereto. Accordingly, endwall 760 has a thickness T_{760} that is equal to the distance between outer surface 788 and inner surface 790 thereof.

In Figure 45 each of slits 764, 766, appears on edge only. Slits 764, 766, are located within endwall 760 in proximity to interior wall 774 on opposite sides thereof. Slit 764 extends through endwall 760 at a position on endwall 760 that affords access to first fluid passageway 776. Correspondingly, slit 766 extends through endwall 760 at a position on endwall 760 that affords access to second fluid passageway 778.

In contrast to the inventive embodiment disclosed in Figures 42-43, the area of first fluid passageway 776 in a transverse cross section of distal extension 768 at proximal end 792 of outer wall 770 is less than the area of first fluid passageway 776 in a transverse cross section of distal extension 768 adjacent endwall 760 at distal end 794 of outer wall 770. Therefore, first fluid passageway 776 includes an enlarged distal terminus 796 at which first portion 782 of inner surface 772 of outer wall 770 flares radially outwardly from longitudinal axis L_{756}, forming a first frustoconical surface 798. In combination with the distal portion of first side 780 of interior wall 774, first frustoconical surface 798 encircles distal terminus 796 of first fluid passageway 776. The periphery 800 of first frustoconical surface 798 takes the form of a small-radius fillet that smoothly connects first frustoconical surface 798 with inner surface 790 of endwall 760. At periphery 800 of first frustoconical surface 798, the thickness of outer wall 770 is identified in Figure 45 as thickness T_{800}.

Second fluid passageway 778 is similarly configured. Thus, second fluid passageway 778 includes an enlarged distal terminus 802 at which second portion 786 of inner surface 772 of outer wall 770 flares radially outwardly from longitudinal axis L_{756} of distal portion 756 to form a second frustoconical surface 804. In combination with the distal portion of second side 784 of interior wall 774, second frustoconical surface 804 encircles distal

terminus 802 of second fluid passageway 778. The periphery 806 of second frustoconical surface 804 takes the form of a small-radius fillet that smoothly connects second frustoconical surface 804 with inner surface 790 of endwall 760. At periphery 806 of second frustoconical surface 804, the thickness of outer wall 770 is identified in Figure 45 as a thickness T_{806}.

The transverse cross section of the exterior of outer wall 770 of distal extension 768 is unchanged along the full length thereof. Therefore, at distal terminus 796 of first fluid passageway 776, first frustoconical surface 798 produces a corresponding first tapered wall structure 801 at distal end 794 of outer wall 770. The thickness of first tapered wall structure 801 and of outer wall 770 in the vicinity of first fluid passageway 776 reaches a minimum at periphery 800 of first frustoconical surface 798 that is equal to thickness T_{800}. Distal of periphery 800 of first frustoconical surface 798, outer wall 770 of distal extension 768 increases in thickness.

For similar reasons, second frustoconical surface 804 produces a correspondingly configured second tapered wall structure 807 at distal end 794 of outer wall 770. The thickness of second tapered wall structure 807 and of outer wall 770 in the vicinity of second fluid passageway 778 reaches a minimum at periphery 806 of second frustoconical surface 804 that is equal to thickness T_{806}. Distal of periphery 806 of second frustoconical surface 804, outer wall 770 of distal extension 768 increases in thickness.

The reduction in the thickness of outer wall 770 at first tapered wall structure 801 and at second tapered wall structure 807 correspondingly and advantageously permits an enhancement of the diametrical extent of endwall 760. The increase thusly afforded in the diametrical extent of endwall 760 is directly related to the amount of the thinning of outer

wall 770 at periphery 800 of first frustoconical surface 798 and at periphery 806 of second frustoconical surface 804. Accordingly, as illustrated in Figure 45, the minimum diametrical extent E_{760min} is larger than diameter D_{574} of inner surface 574 of outer wall 572 of catheter tube 566. Similarly, but as illustrated in Figure 46, the maximum diametrical extent E_{760max} of endwall 760 is larger than diameter D_{574} of inner surface 574 of outer wall 572 of catheter tube 566. Maximum diametrical extent E_{760max} of endwall 760 is, however, enhanced in part due to the inclination of endwall 760 relative to longitudinal axis L_{756} of distal portion 756.

As slits 764, 766, are substantially similar in structural detail, only features of slit 764 will be described further herein. Slit 764 is contained in the plane identified by section line 46-46 in Figures 44-45. Accordingly, Figure 46 depicts only a first slit face 808 of the two opposed slit faces that are normally engaged in the closed position of slit 764 in which first fluid passageway 776 is isolated from the exterior of distal portion 756 of catheter device 754.

Slit face 808 is an elongated, substantially parallelogrammatic surface bounded along the longer extent thereof by an outer edge 810 and an inner edge 812 that is parallel thereto. The opposite ends of inner edge 812 each terminate in a small-radius corner fillet corresponding to the corner fillet that smoothly connects first frustoconical surface 798 to inner surface 790 of endwall 760. Otherwise, inner edge 812 of slit face 808 corresponds to inner surface 790 of endwall 760. Outer edge 810 of slit face 808 coincides with outer surface 788 of endwall 760.

At the extreme ends of slit face 808, the opposed edges of outer edge 810 and inner edge 812 are joined by respective slit face junctions 814, 816, at which the opposed ends of the slit faces of slit 764 are permanently secured together. The distance between slit face junctions 814, 816 defines the length S_{764} of slit 764. As shown in Figure 46, length S_{764} is

substantially larger than diameter D_{574} of inner surface 574 of outer wall 572 and larger than diameter D_{566} of the exterior of catheter tube 566.

Slit face junctions 814, 816, are shown in Figure 46 by way of illustration as being parallel with each other and with longitudinal axis L_{756} of distal portion 756. Nonetheless, specific desirable functional characteristics of a slit, such as slit 764 operated as a valve, may dictate that slit face junctions 814, 816, be nonparallel, be oriented individually at equal or unequal acute or obtuse angles, respectively, relative to outer edge 810 of slit face 808, or be located proximally along outer wall 770 of distal extension 768 from the position thereof illustrated in Figure 46.

The three positions assumable by slits 764, 766, when operated individually or together as valves are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the operation of slits 764, 766, in endwall 760 when operated individually or together as valves are similar to those described in relation to each of these sets of figures, with the qualification resulting from the inclination of endwall 760, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28-29.

Steps in a method for manufacturing an inclined planar endwall of uniform thickness and enhanced maximum diametrical extent, such as endwall 760 in which to form a slit or slits to be used as a valve or valves, respectively, are similar to those presented in the sequence of Figures 22A-22G, except that dual lumen tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. The fusion bonding technique presented among those figures was not utilized to manufacture catheter device 754, but that technique does present an

acceptable alternative approach to indirectly securing distal extension 768 to catheter tube 566 at distal surface 608 of outer wall 572 and at distal surface 610 of septum 576.

Regardless of the method used to manufacture catheter device 754, the material properties of endwall 760 need not be identical to those of outer wall 572 and of septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

The positioning and configuration of one or more slits formed according to teachings of the present invention in the endwall of a dual lumen catheter device need not be exclusively as depicted in Figures 44-46. Linear slits, such as slits 764, 766, are relatively easy to form and are possessed of relatively predictable behavior.

The positioning of slits, such as slit 764, 766, in a parallel relationship in close proximity to the septum or interior wall of the catheter device through which the slits are formed produces slits of maximum length relative to the dimensions of the endwall involved. Specific medical applications can, however, require that alternative arrangements be adopted. Accordingly, depicted in Figure 47 is an enlarged view of distal portion 756 of catheter device 754 with a sequence of various possible alternative orientations of and positions for a slit, such as slit 764 associated with first fluid passageway 776 therein. Slit 764 is shown in the same position and orientation thereof as is illustrated in Figures 44-46.

Length S_{764} of slit 764 associated with first fluid passageway 776 can be decreased by altering the orientation or the position of the slit within the portion of endwall 760 that affords access to first fluid passageway 776. Thus, for example, slit 764-1, which like slit 764 is

parallel to interior wall 774, is shorter in length than slit 764, because slit 764-1 is positioned on endwall 760 further from interior wall 774 than is slit 764.

Slit 764-2 is positioned in endwall 760 yet further from interior wall 774 than slit 764-1. Accordingly, slit 764-2 is shorter than slit 764-1, although the length-shortening effect of the positioning of slit 764-2 remote from interior wall 774 is reduced somewhat, because slit 764-2 is oriented at an acute angle to interior wall 774, rather than being parallel thereto.

Slit 764-3 is positioned in endwall 760 even more remote from interior wall 774 than is slit 764-2. To reduce the length-shortening effect of this relative positioning of slit 764-3, slit 764-3 is oriented at a larger acute angle to interior wall 774 than is slit 764-2.

Slit 764-4 is in a diametrical relationship to endwall 760 and in a perpendicular relationship to interior wall 774. This defines a slit of intermediate length relative to the dimensions of endwall 760. Even shorter slit lengths within the portion of endwall 760 through which first fluid passageway 776 is accessible can be achieved. Accordingly, a slit, such as slit 764-4, could be positioned within endwall 760 radially offset from longitudinal axis L_{756} of distal portion 756 in a manner similar to the radially offset positioning in endwall 80 of slit 84 illustrated in Figures 6-8. A slit offset in this manner from the position of slit 764-4 illustrated in Figure 47 would, if oriented perpendicularly to interior wall 774, have a length less than the length of slit 764-4.

Finally, slit 764-5, which is also parallel to internal wall 774, has a greater length than even slit 764, because slit 764-5 traverses the full width of endwall 760 in close proximity to

interior wall 774. Accordingly, the visible outer edge of slit 764-5 assumes a 90-degree bend at elliptical periphery 762 of endwall 760.

Each of slit 764-1, slit 764-2, slit 764-3, slit 764-4, and slit 764-5 is an example of structure capable of performing the three functions of a selectively operable fluid transport means relative to first fluid passageway 776 according to teachings of the present invention.

Regardless of the method used to manufacture an inclined planar endwall of enhanced diametrical extent, such as endwall 710 in Figures 42-43 or endwall 760 in Figures 44-47, the relative relationship of such an endwall to any septum or internal wall of the corresponding catheter device is not limited according to the teachings of the present invention to being aligned exclusively either with the minimum diametrical extent of the endwall, as in catheter device 704 in Figures 42-43, or with the maximum diametrical extent of an endwall, as in catheter device 754 illustrated in Figures 44-47.

Accordingly, depicted in Figure 48 by way of example is a fifth embodiment of the distal portion of a dual lumen catheter device 824 that incorporates teachings of the present invention, but that is possessed of contrasting structural characteristics relative to the inventive embodiments illustrated and discussed previously. Catheter device 824 is there seen to have a distal portion 826 with a longitudinal axis L_{826} and a closed distal tip 828. Distal tip 828 includes a circumferential outer wall and a planar terminal endwall 830 continuously supported by that circumferential outer endwall. The periphery 832 of endwall 830 is also located on that circumferential endwall, whereby periphery 832 is the intersection of the outer surface of each.

Periphery 832 of endwall 830 is an ellipse having a maximum diametrical extent E_{830max} measured along the major axis of that ellipse and a minimum diametrical extent E_{830min} measured

perpendicular thereto along the minor axis of that ellipse. Periphery 832 of endwall 830 defines a plane P_{830} that forms an acute orientation angle A_{830} with longitudinal axis L_{826} of distal portion 826 of catheter device 824. Thus, endwall 830 is inclined relative to longitudinal axis L_{826}. Extending diametrically across substantially the full extent of endwall 830 is a pair of distinct, relatively widely separated, parallel slits 834, 836, of equal length.

Catheter device 824 includes catheter tube 566, illustrated previously in cross section in Figure 34, and inclined endwall 830 therefor. Accordingly, catheter tube 566 is a dual lumen catheter tube that includes cylindrical circumferential outer wall 572 with an inner surface 574 and a planar septum 576 that extends between distinct nonadjacent locations on inner surface 574. Consequently, the interior of catheter tube 566 is separated by septum 576 into a pair of longitudinally extending fluid flow lumens 578, 580. Lumen 578 is defined by a first side 582 of septum 576 and a first portion 584 of inner surface 574 of outer wall 572 adjacent to first side 582 of septum 576. Lumen 580 is located on the opposite side of septum 576 from lumen 578, whereby lumen 580 is defined by a second side 586 of septum 576 and a second portion 588 of inner surface 574 of outer wall 572 adjacent to second side 586 of septum 576. Septum 576 is diametrically disposed within the transverse cross section of catheter tube 566, whereby lumens 578, 580, would present identical D-shaped configurations in a transverse cross section of catheter device 824.

Septum 576 is, however, aligned neither with minor diametrical extent E_{830min} of endwall 830 or with maximum diametrical extent E_{830max} thereof. Thus, while slits 834, 836, are parallel to each other, slits 834, 836, are neither parallel to nor perpendicular to septum 576 in catheter device 824. Slit 834 extends through endwall 830 at a position on endwall 830 that

affords access to lumen 578 when slit 834 is operated as a valve. Correspondingly, slit 836 extends through endwall 830 at a position on endwall 830 that affords access to lumen 580 when slit 836 is operated as a valve.

The three positions assumable by slits 834, 836, when operated individually or together as valves are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of the operation of slits 834, 836, in endwall 830 when operated individually or together as valves are similar to those described in relation to each of these sets of figures, with the qualification resulting from the inclination of endwall 830, as discussed in detail in relation to the operation of slit 434 illustrated in Figures 28-29.

Steps in a method for manufacturing an inclined planar endwall, such as endwall 830 in which to form a slit or slits to be used as a valve or valves, respectively, are similar to those presented in the sequence of Figures 5A-5E, except that dual lumen tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. Alternatively, an endwall, such as endwall 830, can be secured to the outer wall 572 of a catheter tube using an intermediary structure, such as the sidewalls of a distal extension for the catheter tube, or a fusion band 276 of the type illustrated in Figures 20-21.

Regardless of the method used to manufacture catheter device 824, the material properties of endwall 830 need not be identical to those of outer wall 572 and of septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

In each inventive dual lumen catheter device disclosed and discussed above, the endwall structure that terminates the distal extent of one of the lumens therein is a structure that is coplanar with the endwall structure that terminates the distal extent of the other of the lumens. Thus, for example, the portion of endwall 600 illustrated in Figures 35-37 through which slit 604 affords access to lumen 578 is coplanar with the portion of endwall 600 through which slit 606 affords access to lumen 580. A similar relationship is also reflected in endwall 640 of catheter device 634 in Figures 39-41, in endwall 710 of catheter device 704 in Figures 42-43, and in endwall 760 of catheter device 754 in Figures 44-46. According to teachings of the present invention, however, such a relationship need not in all instances be maintained between the endwall structures that terminate the distal extent of respective lumens in a catheter device having a plurality of longitudinally extending lumens.

Accordingly, depicted in Figure 49 by way of example is a sixth embodiment of the distal portion of dual lumen catheter device 844 that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive embodiments previously illustrated and disclosed. Catheter device 844 is there seen to have a distal portion 846 with a longitudinal axis L_{846} and a closed distal tip 848.

Distal tip 848 includes a circumferential outer wall, a planar first terminal endwall 850 continuously supported by a portion of that circumferential outer wall, and a planar second terminal endwall 851 that intersects first endwall 850 and is continuously supported by the balance of that circumferential outer wall.

First endwall 850 is bounded by an elliptical periphery 852 and a linear distal edge 853 that is coincident with the minor diametrical axis of that ellipse. Periphery 852 and distal

edge 853 of first endwall 850 define a plane P_{850} of first endwall 850 that forms an acute orientation angle A_{850} with longitudinal axis L_{846} of distal portion 846 of catheter device 844. Thus, first endwall 850 is inclined relative to longitudinal axis L_{846}.

Second endwall 851 is bounded by an elliptical periphery 854 and distal edge 853. Periphery 854 and distal edge 853 define a plane P_{851} of second endwall 851 that forms an acute orientation angle A_{851} with longitudinal axis L_{846} of distal portion 846 of catheter device 844. While the perspective view provided in Figure 49 may appear ambiguously to the contrary, from the elevation cross section view presented in Figure 50, it can be seen that angle of inclination A_{850} of first endwall 850 is equal to angle of inclination A_{851} of second endwall 851.

Extending diametrically across first endwall 850 on the major axis of periphery 852 thereof is the visible outer edge of a linear first slit 856 that is as a result perpendicular to distal edge 853 of first endwall 850. Extending substantially across the full extent of second endwall 851 parallel to distal edge 853 of second endwall 851 is the visible outer edge of a linear second slit 857.

According to an aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of inclined, intersecting non-coplanar terminal endwalls is provided with selectively operable stagnation suppression means associated with one or both of those lumens that performs the function thereof disclosed in detail previously. Each of first slit 856 and first endwall 850 and second slit 857 in second endwall 851 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 844.

According to another aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of inclined, intersecting non-coplanar terminal endwalls is provided with selectively operable fluid transport means associated with one or both of those lumens that performs the three functions thereof disclosed in detail previously. Each of first slit 856 in first endwall 850 and second slit 857 in second endwall 851 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen of catheter device 844.

In the elevation cross section view presented in Figure 50, distal portion 846 of catheter device 844 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 858 therefor. Distal extension 858 has an outer wall 860 with an inner surface 862 and a planar interior wall 864 that extends between distinct nonadjacent locations on inner surface 862. Consequently, the interior of distal extension 858 is separated by interior wall 864 into a first fluid passageway 866 and a second fluid passageway 868. The cross section of lumen 578 of catheter tube 566 is smoothly continuous with the cross section of first fluid passageway 866 at proximal end 870 of outer wall 860 of distal extension 858. The cross section of lumen 580 of catheter tube 566 is similarly smoothly continuous with the cross section of second fluid passageway 868 at proximal end 870 of outer wall 860 of distal extension 858.

First endwall 850 extends across the otherwise open distal end of first fluid passageway 866, while second endwall 851 extends across the otherwise open distal end of second fluid passageway 868. Each of first endwall 850 and second endwall 851 is continuously

supported by a combination of interior wall 864 and a respective portion of outer wall 860 contiguous therewith, but on opposite sides thereof. First endwall 850 and second endwall 851 are secured to outer wall 860 and interior wall 864 of distal extension 858 by any of the appropriate methods discussed previously.

First endwall 850 has an outer surface 874 visible but not labeled in Figure 49 and an inner surface 875 that is parallel thereto. Accordingly, first endwall 850 has a thickness T_{850} that is equal to the distance between outer surface 874 and inner surface 875 thereof. Similarly, second endwall 851 has an outer surface 876 visible but not labeled in Figure 49 and an inner surface 877 that is parallel thereto. Second endwall 851 has a thickness T_{851} that is equal to the distance between outer surface 876 and inner surface 877 thereof. While thickness T_{850} of first endwall 850 is shown in Figure 50 as being equal to thickness T_{851} of second endwall 851, such a relationship is not required according to the teachings of the present invention.

First slit 856 is formed through first endwall 850, thereby to be associated with first fluid passageway 866 when first slit 856 is operated as a valve. Second slit 857 is formed through second endwall 851, thereby to be associated with second fluid passageway 868 when second slit 857 is operated as a valve. In Figure 50, second slit 857 appears on edge only. As first slit 856 is contained in a plane identified by section line 50-50 in Figure 49, Figure 50 depicts a first slit face 878 of the two opposed slit faces that are normally engaged in the closed position of first slit 856. Slit face 878 is an elongated, rectangular surface having a length equal to the length S_{856} of first slit 856 shown in Figure 50. Further structural details of slit face 878 need not be discussed.

The three positions assumable by first slit 856 and second slit 857, when operated individually or together as valves, are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of first slit 856 in first endwall 850 and second slit 857 in second endwall 851 when operated individually or together as valves are similar to those described in relation to each of these sets of figures, with the qualification resulting from the inclination of each of first endwall 850 and second endwall 851, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28 and 29.

Steps in a method for manufacturing inclined, intersecting, non-coplanar endwalls of uniform thickness, such as first endwall 850 and second endwall 851 in which to form respective slits to be used as valves, are similar to those presented in the sequence of Figures 12A-12E, except that dual lumen tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. It should be noted that the manufacture of a pair of inclined, intersecting, non-coplanar endwalls, such as first endwall 850 and second endwall 851, could be implemented according to teachings of the present invention using the fusion bonding technique presented among the sequence of Figures 22A-22G.

Alternatively, a pair of inclined, non-coplanar endwalls of uniform thickness, such as first endwall 850 and second endwall 851, can be attached directly to outer wall 572 and septum 576 of catheter tube 566 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E. Thus, it is possible according to teachings of the present invention to forego resort to any intermediary structure, such as outer wall 860 and interior wall 864 of distal extension 858, in connecting and continuously supporting a pair

of inclined, intersecting, non-coplanar endwalls on the otherwise open distal end of a dual lumen catheter tube.

Regardless of the method used to manufacture catheter device 844, the material properties of first endwall 850 and second endwall 851 need not be identical to those of outer wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 50, it is clear that providing first slit 856 and second slit 857 in first endwall 850 and second endwall 851, respectively, and securing first endwall 850 and second endwall 851 to outer wall 572 and to septum 576 of catheter tube 566, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 844 and at no increase in the size of the outer cross section of distal portion 846 of catheter device 844.

The positioning and configuration of one or more slits formed according to teachings of the present invention in respective inclined, non-coplanar endwalls of a dual lumen catheter device need not be exclusively as depicted in Figures 49-50. Accordingly, depicted in Figure 51 is an enlarged view of distal portion 846 of catheter device 844 with a sequence of various possible alternative orientations and positions for a slit, such as first slit 856 associated with first fluid passageway 866 therein. Second slit 857, which is associated with second fluid passageway 868 when operated as a valve, is shown in the same position and orientation thereof as in Figures 49-50.

The position of a slit, such as first slit 856, in a diametrical relationship to the endwall through which the slit is formed and in a perpendicular relationship to a septum or internal wall that defines a portion of the lumen or fluid passageway with which the slit is associated, produces a slit of intermediate length relative to the dimensions of the endwall involved. Specific medical applications can require that alternative arrangements be adopted.

Accordingly, first slit 856 could, for example, be positioned within first endwall 850 radially offset from longitudinal axis L_{846} of distal portion 846 in a manner similar to the radially offset positioning in endwall 80 of slit 84 illustrated in Figures 6-8. A slit offset in this manner from the position illustrated in Figures 49 and 50 would, if oriented perpendicular to interior wall 864, have a length less than length S_{856} of first slit 856.

On the other hand, length S_{856} of first slit 856 can be increased by altering the orientation or the position of the slit within first endwall 850. Thus, for example, slit 856-1 is greater in length than length S_{856} of first slit 856, because slit 856-1 is oriented at an acute angle, rather than at a right angle, to interior wall 864 of distal extension 858. Slit 856-2 is greater in length than slit 856-1, because slit 856-2 is further inclined away from the perpendicular to interior wall 864 than is slit 856-1. Also, slit 856-2 has been positioned on first endwall 850 closer to interior wall 864 than is slit 856-2.

Slit 856-3 is parallel to interior wall 864. Due to the relative position of slit 856-3 on first endwall 850, slit 856-3 is greater in length than slit 856-2. Slit 856-4 is also parallel to interior wall 864, but slit 856-4 has a greater length than slit 856-3, because slit 856-4 is positioned on first endwall 850 in closer proximity to interior wall 864 than is slit 856-3.

Finally, slit 856-5, which is also parallel to interior wall 864, has a greater length than even slit 856-4, because slit 856-5 traverses the full width of first endwall 850 in close proximity to interior wall 864. Accordingly, the visible outer edge of slit 856-5 assumes a 90-degree bend at elliptical periphery 852 of first endwall 850.

Each of slit 856-1, slit 856-2, slit 856-3, slit 856-4, and slit 856-5 is an example of structure capable of performing the three functions of a selectively operable fluid transport means relative to first fluid passageway 866 according to teachings of the present invention.

Depicted in Figure 52 by way of example is a seventh embodiment of the distal portion of a dual lumen catheter device 884 that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive embodiments previously illustrated and disclosed. Catheter device 884 is there seen to have a distal portion 886 with a longitudinal axis L_{886} and a closed distal tip 888.

Distal tip 888 includes a circumferential outer wall, a first planar terminal endwall 890 continuously supported by a portion of that circumferential outer wall, and a second planar terminal endwall 891 that intersects first endwall 890 and is continuously supported by the balance of that circumferential outer wall.

First endwall 890 is bounded by the combination of an elliptical periphery 892 and a linear distal edge 893 that is coincident with the minor diametrical axis of that ellipse. Periphery 892 and distal edge 893 of first endwall 890 define a plane P_{890} of first endwall 890 that forms an acute orientation angle A_{890} with longitudinal axis L_{886} of distal portion 886 of catheter device 884. Thus, first endwall 890 is inclined relative to longitudinal axis L_{886}.

By contrast, second endwall 891 is bounded by the combination of a semicircular periphery 894 and distal edge 893. Distal edge 893 is thus located both on first endwall 890 and on second endwall 891. Periphery 894 and distal edge 893 define a plane P_{891} of second endwall 891 that is perpendicular to longitudinal axis L_{886} of distal portion 886 of catheter device 884.

Extending diametrically across first endwall 890 on the major axis of periphery 892 thereof is the visible outer edge of a linear first slit 896 that is as a result perpendicular to distal edge 893 of first endwall 890. Extending substantially across the full extent of second endwall 891 parallel to edge 893 of second endwall 891 is the visible outer edge of a linear second slit 897.

According to an aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of intersecting terminal endwalls is provided with selectively operable stagnation suppression means associated with one or both of those lumens that performs the function thereof disclosed in detail previously. Each of first slit 896 in first endwall 890 and second slit 897 in second endwall 891 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 884.

According to another aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of intersecting terminal endwalls is provided with selectively operable fluid transport means associated with one or both of those lumens that performs the three functions thereof disclosed

in detail previously. Each of first slit 896 in first endwall 890 and second slit 897 in second endwall 891 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen of catheter device 884.

In the elevation cross section view presented in Figure 53, distal portion 886 of catheter device 884 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 898 therefor. Distal extension 898 has an outer wall 900 with an inner surface 902 and a planar interior wall 904 that extends between distinct nonadjacent locations on inner surface 902. Consequently, the interior of distal extension 898 is separated by interior wall 904 into a first fluid passageway 906 and a second fluid passageway 908. The cross section of lumen 578 of catheter tube 566 is smoothly continuous with the cross section of first fluid passageway 906 at proximal end 910 of outer wall 900 of distal extension 898. The cross section of lumen 580 of catheter tube 566 is similarly smoothly continuous with the cross section of second fluid passageway 908 at proximal end 910 of outer wall 900 of distal extension 898.

First endwall 890 extends across the otherwise open distal end of first fluid passageway 906, while second endwall 891 extends across the otherwise open distal end of second fluid passageway 908. Each of first endwall 890 and second endwall 891 is continuously supported by a combination of interior wall 904 and a respective portion of outer wall 900 contiguous therewith, but on opposite sides thereof. First endwall 890 and second endwall 891 are secured to outer wall 900 and to interior wall 904 of distal extension 898 by any of the appropriate methods discussed previously.

First endwall 890 has an outer surface 914 visible but not labeled in Figure 52 and an inner surface 915 that is parallel thereto. Accordingly, first endwall 890 has a thickness T_{890} that is equal to the distance between outer surface 914 and inner surface 915 thereof. Similarly, second endwall 891 has an outer surface 916 visible but not labeled in Figure 52 and an inner surface 917 that is parallel thereto. Second endwall 891 has a thickness T_{891} that is equal to the distance between outer surface 916 and inner surface 917 thereof. While thickness T_{890} of first endwall 890 is shown in Figure 53 as being equal to thickness T_{891} of second endwall 891, such a relationship is not required according to teachings of the present invention.

First slit 896 is formed through first endwall 890, thereby to be associated with first fluid passageway 906 when first slit 896 is operated as a valve. Second slit 897 is formed through second endwall 891, thereby to be associated with second fluid passageway 908 when second slit 897 is operated as a valve. In Figure 53, second slit 897 appears on edge only. As first slit 896 is contained in a plane identified by section line 53-53 in Figure 52, the view presented in Figure 53 includes a first slit face 918 of the two opposed slit faces that are normally engaged in the closed position of first slit 896. Slit face 918 is an elongated, rectangular surface having a length equal to length S_{896} of first slit 896 shown in Figure 53. Further structural details of slit face 918 need not be discussed.

The three positions assumable by first slit 896 and second slit 897, when operated individually or together as valves, are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of first slit 896 in first endwall 890 when operated as a valve are similar to those described in relation to each of these figures, with the qualification resulting

from the inclination of first endwall 890, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28 and 29. By contrast, due to the perpendicular orientation of second endwall 891 to longitudinal axis L_{886} of distal portion 886 of catheter device 884, the advantages of the operation of second slit 897 in second endwall 891 when operated as a valve are similar without qualification to those described in relation to the sets of figures listed above.

Steps in a method for manufacturing intersecting endwalls, such as first endwall 890 and second endwall 891 in which to form respective slits to be used as valves, are similar to those presented in the sequence of Figures 12A-12E, except that dual lumen tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. It should be noted that the manufacture of a pair of intersecting endwalls, such as first endwall 890 and second endwall 891, could be implemented according to teachings of the present invention using the fusion bonding technique presented among the sequence of Figures 22A-22G.

Alternatively, a pair of intersecting endwalls, such as first endwall 890 and second endwall 891, can be attached directly to outer wall 572 and septum 576 of catheter tube 566 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E. Thus, it is possible according to teachings of the present invention to forego resort to any intermediary structure, such as outer wall 900 and interior wall 904 of distal extension 898, in connecting and continuously supporting a pair of intersecting endwalls on the otherwise open distal end of a dual lumen catheter tube.

Regardless of the method used to manufacture catheter device 884, the material properties of first endwall 890 and second endwall 891 need not be identical to those of outer

wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 53, it is clear that providing first slit 896 and second slit 897 in first endwall 890 and second endwall 891, respectively, and securing first endwall 890 and second endwall 891 to outer wall 572 and to septum 576 of catheter tube 566, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 884 and at no increase in the size of the outer cross section of distal portion 886 of catheter device 884.

In each inventive dual lumen catheter device disclosed and discussed above, the endwall structure that terminates the distal extent of one of the lumens therein is a structure that is intersecting of the endwall structure that terminates the distal extent of the other of the lumens. Thus, for example, first endwall 850 and second endwall 851 illustrated in Figures 49-51 intersect at common edge 853. A similar relationship is also reflected between first endwall 890 and second endwall 891 illustrated in Figures 52-53. According to teachings of the present invention, however, such a relationship need not in all instances be maintained between the endwall structures that terminate the distal extent of respective lumens in a catheter device having a plurality of longitudinally extending lumens.

Accordingly, depicted in Figure 54 by way of example is an eighth embodiment of the distal portion of a dual lumen catheter device 924 that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive

embodiments previously illustrated and disclosed. Catheter device 924 is there seen to have a distal portion 926 with a longitudinal axis L_{926} and a closed distal tip 928.

Distal tip 928 includes a circumferential outer wall, a planar first endwall 929 continuously supported by a portion of that circumferential outer wall, a planar second endwall 930 continuously supported by the balance of that circumferential outer wall, and a rectangular endwall interconnection bridge 931. Second endwall 930 is thus neither coplanar with nor intersecting of first endwall 929. Instead, first endwall 929 and second endwall 930 are staggered relative to each other at distal tip 928 of catheter device 924.

Endwall interconnection bridge 931 is bounded on the sides thereof that are parallel to longitudinal axis L_{926} by the circumferential outer wall of distal tip 928. First endwall 929 and second endwall 930 are thus staggered relative to each other. Therebetween, the opposite ends of endwall interconnection bridge 931 are bounded by first endwall 929 and second endwall 930, respectively.

First endwall 929 is bounded by the combination of an elliptical periphery 932 and a linear distal edge 933 that is coincident with the minor diametrical axis of that ellipse. Periphery 932 and distal edge 933 of first endwall 929 define a plane P_{929} of first endwall 929 that forms an acute orientation angle A_{929} with longitudinal axis L_{926} of distal portion 926 of catheter device 924. Thus, first endwall 929 is inclined relative to longitudinal axis L_{926}.

Second endwall 930 is bounded by the combination of a circular periphery 934 and edge 935. Periphery 934 and edge 935 define a plane P_{930} of second endwall 930 that is perpendicular to longitudinal axis L_{926} of distal portion 926 of catheter device 924. As first endwall 929 and second endwall 930 do not form equal orientation angles with longitudinal

axis L_{926} of distal portion 926, first endwall 929 and second endwall 930 are not parallel. As previously mentioned, first endwall 929 and second endwall 930 are non-coplanar and nonintersecting. For convenience hereinafter, endwalls, such as first endwall 929 and second endwall 930 that are nonparallel, non-coplanar, and nonintersecting, will be referred to as being skewed.

Extending diametrically across first endwall 929 on the major axis of periphery 932 thereof is the visible outer edge of a first slit 936 that is as a result perpendicular to distal edge 933 of first endwall 929. Extending substantially across the full extent of second endwall 930 parallel to edge 935 of second endwall 930 is the visible outer edge of a linear second slit 937.

According to an aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of skewed terminal endwalls is provided with selectively operable stagnation suppression means associated with one or both of those lumens that performs the function thereof disclosed in detail previously. Each of first slit 936 in first endwall 929 and second slit 937 in second endwall 930 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 924.

According to another aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of skewed terminal endwalls is provided with selectively operable fluid transport means associated with one or both of those lumens that performs the three functions thereof disclosed in detail

previously. Each of first slit 936 in first endwall 929 and second slit 937 in second endwall 930 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen of catheter device 924.

In the elevation cross section view presented in Figure 55, distal portion 926 of catheter device 924 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 938 therefor. Distal extension 938 has an outer wall 940 with an inner surface 942 and a planar interior wall 944 that extends between distinct nonadjacent locations on inner surface 942. Consequently, the interior of distal extension 938 is separated by interior wall 944 into a first fluid passageway 946 and a second fluid passageway 948. The cross section of lumen 578 of catheter tube 566 is smoothly continuous with the cross section of first fluid passageway 946 at proximal end 950 of outer wall 940 of distal extension 938. The cross section of lumen 580 of catheter tube 566 is similarly smoothly continuous with the cross section of second fluid passageway 948 at proximal end 950 of outer wall 940 of distal extension 938.

First endwall 929 extends across the otherwise open distal end of first fluid passageway 946, and is continuously supported by a combination of interior wall 944 and a portion of outer wall 940 contiguous therewith. From Figure 55 it is apparent that endwall interconnection bridge 931 is an extension of interior wall 944 distally beyond first endwall 929. Second endwall 930 extends across the otherwise open distal end of second fluid passageway 948, and is continuously supported by the combination of endwall interconnection bridge 931 and a respective portion of outer wall 940 contiguous therewith. First endwall 929,

second endwall 930, and endwall interconnection bridge 931 are secured to outer wall 940 and interior wall 944 of distal extension 938 by any of the appropriate methods discussed previously.

First endwall 929 has an outer surface 954 visible but not labeled in Figure 54 and an inner surface 955 that is parallel thereto. Accordingly, first endwall 929 has a thickness T_{929} that is equal to the distance between outer surface 954 and inner surface 955 thereof. Similarly, second endwall 930 has an outer surface 956 visible but not labeled in Figure 54 and an inner surface 957 that is parallel thereto. Second endwall 930 has a thickness T_{930} that is equal to the distance between outer surface 956 and inner surface 957 thereof. While thickness T_{929} of first endwall 929 is shown in Figure 55 as being equal to thickness T_{930} of second endwall 930, such a relationship is not required according to the teachings of the present invention.

First slit 936 is formed through first endwall 929, thereby being associated with first fluid passageway 946 when first slit 936 is operated as a valve. Second slit 937 is formed through second endwall 930, thereby being associated with second fluid passageway 948 when second slit 937 is operated as a valve. In Figure 55, second slit 937 appears on edge only. As first slit 936 is contained in the plane identified by section line 55-55 in Figure 54, the view presented in Figure 55 depicts a first slit face 958 from among the pair of opposed slit faces that are mutually engaged in the closed position of first slit 936. Slit face 958 is an elongated, rectangular surface having a length equal to the length S_{936} of first slit 936 shown in Figure 55. Further structural details of slit face 958 need not be discussed.

The three positions assumable by first slit 936 and second slit 937, when operated individually or together as valves, are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354.

Correspondingly, the advantages of first slit 936 and second slit 937 when operated individually or together as valves are similar to those described in relation to each of these sets of figures, with the qualification relative to first slit 936 resulting from the inclination of first endwall 929, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28 and 29.

Steps in a method for manufacturing skewed endwalls, such as first endwall 929 and second endwall 930 in which to form respective slits to be used as valves, are similar to those presented in the sequence of Figures 12A-12E, except that dual lumen tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. It should be noted that the manufacture of a pair of skewed endwalls, such as first endwall 929 and second endwall 930, could be implemented according to teachings of the present invention using the fusion bonding technique presented among the sequence of Figures 22A-22G.

Alternatively, a pair of skewed endwalls, such as first endwall 929 and second endwall 930, can be attached directly to outer wall 572 and septum 576 of catheter tube 566 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E. Thus, it is possible according to teachings of the present invention to forego resort to any intermediary structure, such as outer wall 940 and interior wall 944, in connecting and continuously supporting a pair of skewed endwalls on the otherwise open distal end of a dual lumen catheter tube.

Simultaneously with so doing, an endwall interconnection bridge, such as endwall interconnection bridge 931, is secured directly to outer wall 572 and septum 576. In the alternative, by trimming the end of catheter tube 566 without removing the portion of

septum 576 between the planned pair of skewed endwalls, the portion of septum 576 therebetween becomes such an endwall interconnection bridge, and the skewed endwalls are attached directly to the opposite ends thereof.

Regardless of the method used to manufacture catheter device 924, the material properties of first endwall 929, of second endwall 930, and optionally of endwall interconnection bridge 931 need not be identical to those of outer wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 55, it is clear that providing first slit 936 and second slit 937 in first endwall 929 and second endwall 930, respectively, and securing first endwall 929 and second endwall 930 to outer wall 572 and to septum 576 of catheter tube 566, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 924 and at no increase in the size of the outer cross section of distal portion 926 of catheter device 924.

Depicted in Figure 56 by way of example is a ninth embodiment of the distal portion of a dual lumen catheter device 964 that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive embodiments previously illustrated and disclosed. Catheter device 964 is there seen to have a distal portion 966 with a longitudinal axis L_{966} and a closed distal tip 968.

Distal tip 968 includes a circumferential outer wall, a planar first endwall 969 continuously supported by a portion of that circumferential outer wall, a planar second terminal

endwall 970 continuously supported by the balance of that circumferential outer wall, and an endwall interconnection bridge 971.

First endwall 969 and second endwall 970 are thus staggered relative to each other at distal tip 968 of catheter device 964.

Endwall interconnection bridge 971 is bounded on the sides thereof that are parallel to longitudinal axis L_{966} by the circumferential outer wall of distal tip 968. Therebetween, the opposite ends of endwall interconnection bridge 971 are bound by first endwall 969 and second endwall 970, respectively.

First endwall 969 is bounded by the combination of semicircular periphery 972 and a diametrically disposed linear edge 973. Periphery 972 and edge 973 of first endwall 969 define a plane P_{969} of first endwall 969 that is perpendicular to longitudinal axis L_{966} of distal portion 966 of catheter device 964. Similarly, second endwall 970 is bounded by a semicircular periphery 974 and a diametrically disposed linear edge 975. Periphery 974 and edge 975 define a plane P_{970} of second endwall 970 that is perpendicular to longitudinal axis L_{966} of distal portion 966 of catheter device 964. Thus, first endwall 969 and second endwall 970 are parallel to each other.

Extending across substantially the full extent of first endwall 969 parallel to edge 973 thereof is the visible outer edge of a first slit 976. Extending across substantially the full extent of second endwall 970 parallel to edge 975 thereof is the visible outer edge of a second slit 977. Second slit 977 is equal in length to the length of first slit 976.

According to an aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of

parallel terminal endwalls is provided with selectively operable stagnation suppression means associated with one or both of those lumens that performs the function thereof disclosed in detail previously. Each of first slit 976 in first endwall 969 and second slit 977 in second endwall 970 is an example of structure capable of performing the function of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 964.

According to another aspect of the present invention, a catheter tube having a pair of longitudinally extending fluid flow lumens and a distal end closed by a corresponding pair of parallel terminal endwalls is provided with selectively operable fluid transport means associated with one or both of those lumens that performs the three functions thereof disclosed in detail previously. Each of first slit 976 in first endwall 969 and second slit 977 in second endwall 970 is an example of structure capable of performing these functions of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen of catheter device 964.

In the elevation cross section view presented in Figure 57, distal portion 966 of catheter device 964 is seen to include the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 986. The interior of distal extension 986 is separated into a first fluid passageway 979 and a second fluid passageway 980. The cross section of lumen 578 of catheter tube 566 is smoothly continuous with the cross section of first fluid passageway 979, while the cross section of lumen 580 of catheter tube 566 is similarly smoothly continuous with the cross section of second fluid passageway 980.

First endwall 969 extends across the otherwise open distal end of first fluid passageway 979, while second endwall 970 extends across the otherwise open distal end of second fluid passageway 980.

First slit 976 is formed through first endwall 969, thereby being associated with first fluid passageway 979 when first slit 976 is operated as a valve. Second slit 977 is formed through second endwall 970, thereby being associated with second fluid passageway 980 when second slit 977 is operated as a valve. In Figure 57, first slit 976 and second slit 977 appear on edge only.

The three positions assumable by first slit 976 and second slit 977, when operated individually or together as valves, are similar to those illustrated in Figures 4A-4C relative to slit 32, in Figures 11A-11C relative to slit 124, and in Figures 25A-25C relative to slit 354. Correspondingly, the advantages of first slit 976 and second slit 977 when operated individually or together as valves are similar to those described in relation to each of those sets of figures.

Steps in a method for manufacturing a pair of parallel planar endwalls, such as first endwall 969 and second endwall 970 in which to form respective slits to be used as valves, are similar to those presented in the sequence of Figures 12A-12E, except that dual lumen tubing is employed and a distinct mandrel is utilized to occupy each of the lumens thereof. It should be noted that the manufacture of a pair of parallel endwalls, such as first endwall 969 and second endwall 970, could be implemented according to teachings of the present invention using the fusion bonding technique presented among the sequence of Figures 22A-22G. Alternatively, a pair of parallel endwalls, such as first endwall 969 and second endwall 970, can be attached

directly to outer wall 572 and septum 576 of catheter tube 566 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E.

Regardless of the method used to manufacture catheter device 964, the material properties of first endwall 969, of second endwall 970, and optionally of endwall interconnection bridge 971 need not be identical to those of outer wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 57, it is clear that providing first slit 976 and second slit 977 in first endwall 969 and second endwall 970, respectively, and securing first endwall 969 and second endwall 970 to outer wall 572 and to septum 576 of catheter tube 566 are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 964 and at no increase in the size of the outer cross section of distal portion 966 of catheter device 964.

Figure 58 depicts a tenth embodiment of a dual lumen catheter device 984 having a distal portion that incorporates teachings of the present invention and that is possessed of structural features that contrast with the inventive embodiments previously illustrated and disclosed. Catheter device 984 is there seen to have a distal portion 985 with a longitudinal axis L_{985}. Distal portion 985 of catheter device 984 includes the distal end of catheter tube 566, illustrated previously in cross section in Figure 34, and a hollow distal extension 986. The interior of distal extension 986 is separated into a first fluid passageway 987 and a second fluid passageway 988. The cross sections of lumens 578, 580, of catheter tube 566 are smoothly continuous, respectively, with the cross section of first fluid passageway 987 and second fluid

passageway 988. An inclined planar first endwall 989 extends across the otherwise open distal end of first fluid passageway 987, while an inclined second endwall 990 extends across the otherwise open distal end of second fluid passageway 988. First endwall 989 and second endwall 990 do not intersect and, accordingly, are separated along longitudinal axis L_{985} of distal portion 985 by endwall interconnection bridge 991.

A first slit 992 is formed through first endwall 989, thereby to function as a valve for first fluid passageway 987. A second slit 993 is formed through second endwall 990, thereby to function as a valve for second fluid passageway 988.

The three positions assumable by first slit 992 and second slit 993 when operated individually or together as valves are similar to those illustrated in Figures 4A-4C, in Figures 11A-11C, and in Figures 25A-25C. Correspondingly, the advantages of first slit 992 and second slit 993 when operated individually or together as valves are similar to those described in relation to each of those sets of figures, with the qualification resulting from the inclination of each of first endwall 989 and second endwall 990, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28 and 29.

Steps in a method for manufacturing catheter device 984 are similar to those presented in the sequence of Figures 12A-12E, except that the dual lumen tubing is employed and a distinct mandrel is used to occupy each of the lumens thereof. A catheter device, such as catheter device 984, can in the alternative be manufactured using the fusion bonding technique presented among the sequence of Figures 22A-22G. Alternatively, a pair of skewed endwalls, such as first endwall 989 and second endwall 990, can be attached directly to outer wall 572 and septum 576 of catheter tube 566 using the steps of the methods presented in the sequence of

Figures 5A-5E or in the sequence of Figures 9A-9E. In the alternative, by trimming the end of catheter tube 566 without removing the portion of septum 576 between the planned pair of skewed endwalls, the portion of septum 576 therebetween becomes an endwall interconnection bridge, and the skewed endwalls are attached directly to the opposite ends thereof.

Regardless of the method used, however, the material properties of first endwall 989, of second endwall 990, and optionally of endwall interconnection bridge 991 need not be identical to those of outer wall 572 and septum 576 of catheter tube 566. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

From Figure 58, it is clear that providing first slit 992 and second slit 993 in first endwall 989 and second endwall 990, respectively, and securing first endwall 989 and second endwall 990 to outer wall 572 and septum 576 of catheter tube 566, are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 984 and at no increase in the size of the outer cross section of distal portion 985 of catheter device 984.

The teachings of the present invention have equal applicability to catheter devices having three or more longitudinally extending fluid flow lumens. In any catheter device having a plurality of such lumens, one or more of those lumens can have closed distal ends valved by slit structures of the types previously illustrated and discussed, while any others of the lumens can have open distal ends.

Accordingly, depicted in Figures 59-60 by way of example is a first embodiment of a distal portion of a triple lumen catheter device 1004 that incorporates teachings of the present

invention. Catheter device 1004 is there seen to have a distal portion 1006 with a longitudinal axis L_{1006} and a distal tip 1008 closed in part by a planar endwall 1010. Endwall 1010 has a circular periphery 1012 that defines a plane P_{1010} that is perpendicular to longitudinal axis L_{1006}. A circular aperture 1014 is formed through a central portion of endwall 1010. Extending across endwall 1010 on opposite sides of aperture 1014 are a first slit 1016 and a second slit 1018 that is parallel thereto and of equal length therewith.

Each of first slit 1016 and second slit 1018 is an example of structure capable of performing the function disclosed in detail previously of a selectively operable stagnation suppression means according to teachings of the present invention for an associated lumen of catheter device 1004. Each of first slit 1016 and second slit 1018 is also an example of structure capable of performing the three functions disclosed in detail previously of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen within catheter device 1004.

As understood from the transverse elevation cross section view of distal portion 1006 of catheter device 1004 presented in Figure 60, aperture 1014 in endwall 1010 is the distal opening of a centrally disposed circular lumen 1020 positioned within a septum 1022 that otherwise separates the interior of catheter device 1004 into a pair of relatively larger substantially D-shaped lumens 1024, 1026. Circular lumen 1020 enables the use of catheter device 1004 with a guide wire.

First slit 1016 is formed in a portion of endwall 1010 that affords access to lumen 1024. Correspondingly, second slit 1018 is formed in a portion of endwall 1010 that affords access to lumen 1026. First slit 1016 and second slit 1018 when operated individually

or together as valves can assume the three positions illustrated in Figures 4A-4C, in Figures 11A-11C, and in Figures 25A-25C.

Catheter device 1004 can be manufactured by any of the several methods of manufacture illustrated and discussed heretofore, except that triple lumen tubing having a cross sectional configuration like that shown in Figure 60 is employed and a distinct mandrel is used to occupy each of the lumens thereof, including circular lumen 1020 for which no endwall is manufactured. Catheter device 1004 can be manufactured using the fusion bonding technique presented among the sequence of Figures 22A-22G. Alternatively, endwall 1010 can be attached directly to septum 1022 and the circumferential outer wall of catheter device 1004 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E.

As a result, the material properties of endwall 1010 need not be identical to those of septum 1022 or of the outer walls of catheter device 1004. The advantageousness of this aspect of the teachings of the present invention has been discussed in relation to the inventive embodiments previously disclosed herein.

The provision of first slit 1016 and second slit 1018 in endwall 1010, and the securing of endwall 1010 to septum 1022 and to the circumferential outer wall of catheter device 1004, are accomplished at no loss in the size of the cross section of the three longitudinally extending fluid flow lumens within catheter device 1004 and at no increase in the size of the outer cross section of distal portion 1006 of catheter device 1004.

The configuration of lumens in a catheter device having three or more longitudinally extending lumens can vary strikingly, as can the application thereto of teachings of the present

invention. Accordingly, depicted by way of further example in Figures 61-62 is a second embodiment of the distal portion of a triple lumen catheter device 1034 that incorporates teachings of the present invention. Catheter device 1034 is there seen to have a distal portion 1036 with a longitudinal axis L_{1036} and a closed distal tip 1038.

Distal tip 1038 includes a circumferential outer wall, a planar first terminal endwall 1040 continuously supported by a portion of that circumferential outer wall, and a planar second terminal endwall 1042 that intersects first endwall 1040 and is continuously supported by the balance of that circumferential outer wall.

First endwall 1040 is bounded by an elliptical periphery 1044 and a linear distal edge 1043 that is coincident with the minor diametrical axis of that ellipse. Periphery 1044 and distal edge 1043 of first endwall 1040 define a plane P_{1040} of first endwall 1040 that forms an acute orientation angle A_{1040} with longitudinal axis L_{1036} of distal portion 1036 of catheter device 1034. Thus, first endwall 1040 is inclined relative to longitudinal axis L_{1036}.

Second endwall 1042 is bounded by a semicircular periphery 1046 and edge 1043. Periphery 1046 and distal edge 1043 define a plane P_{1042} of second endwall 1042 that is perpendicular to longitudinal axis L_{1036} of distal portion 1036 of catheter device 1034.

Extending across first endwall 1040 are a linear first slit 1048 and a linear second slit 1050 oriented at an angle relative thereto. First slit 1048 and second slit 1050 are of substantially equal length. Extending substantially across the full extent of second endwall 1042 parallel to edge 1043 of second endwall 1042 is the visible outer edge of a linear third slit 1052.

Each of first slit 1048, second slit 1050 and third slit 1052 is an example of structure capable of performing the function disclosed in detail previously of a selectively operable

stagnation suppression means according to teachings of the present invention for an associated lumen within catheter device 1034. Each of first slit 1048, second slit 1050, and third slit 1052 is also an example of structure capable if performing the three functions disclosed in detail previously of a selectively operable fluid transport means according to teachings of the present invention for an associated lumen within catheter device 1034.

In the transverse elevation cross section view presented in Figure 62, the interior of catheter device 1034 can be seen to be subdivided into three longitudinally extending fluid flow lumens by a septum 1054 that assumes a generally T-shaped configuration. Septum 1054 includes a first septum segment 1056, a second septum segment 1058, and a third septum segment 1060 that meet at a common end 1061 of each. The ends of the septum segments 1056, 1058, and 1060, opposite from common end 1061 intersect the interior of catheter device 1034 at distinct locations. Second septum segment 1058 and third septum segment 1060 are aligned in a coplanar relationship.

As a result, a wedge-shaped first lumen 1062 is formed between first septum segment 1056, second septum segment 1058, and the portion of the interior of catheter device 1034 that interconnects the ends of each opposite from common end 1061. Similarly, a wedge-shaped second lumen 1064 is formed between first septum segment 1056, third septum segment 1060, and the portion of the interior of catheter device 1034 that interconnects the ends of each opposite from common end 1061. Finally, a semicircular third lumen 1068 is formed between second septum segment 1058, third septum segment 1060, and a semicylindrical portion of the interior of catheter device 1034 that interconnects the ends of each opposite from common end 1061.

First slit 1048 is formed through first endwall 1040 at a position thereon that affords access to wedge-shaped second lumen 1064, while second slit 1050 is formed through a portion of first endwall 1040 that affords access to wedge-shaped first lumen 1062. Third slit 1052 formed through second endwall 1042 is associated with semicircular third lumen 1068.

When operated individually or together as valves, each of first slit 1048, second slit 1050, and third slit 1052 can assume the three positions illustrated in Figures 4A-4C, in Figures 11A-11C, and in Figures 25A-25C. Correspondingly, when operated individually or together as valves, advantages similar to those described in relation to those sets of figures are obtained, with the qualification relative to the operation of first slit 1048 and second slit 1050 resulting from the inclination of first endwall 1040, as already discussed in detail in relation to the operation of slit 434 illustrated in Figures 28 and 29.

Steps in the method for manufacturing catheter device 1034 are similar to those presented in the sequence of Figures 12A-12E, except that triple lumen tubing having a cross-sectional configuration like that shown in Figure 62 is employed and a distinct mandrel is utilized to occupy each of the three lumens thereof. Catheter device 1034 can be manufactured using the fusion bonding technique presented among the sequence of Figures 22A-22G. Alternatively, first endwall 1040 and second endwall 1042 can be attached directly to septum 1054 and to the circumferential outer wall of catheter device 1034 using the steps of the methods presented in the sequence of Figures 5A-5E or in the sequence of Figures 9A-9E.

Regardless of the method used, however, the material properties of first endwall 1040 and second endwall 1042 need not be identical to those of septum 1054 or of the outer wall of catheter device 1034. The advantageousness of this aspect of the teachings of the present

invention has been discussed in relation to the inventive embodiments previously disclosed herein.

The providing of first slit 1048 and second slit 1050 in first endwall 1040 and third slit 1052 in second endwall 1042, and the securing of first endwall 1040 and second endwall 1042 to septum 1054 and to the outer wall of catheter device 1034 are accomplished at no loss in the size of the cross section of the longitudinally extending fluid flow lumens within catheter device 1034 and at no increase in the size of the outer cross section of distal portion 1036 of catheter device 1034.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.